monly known as the "Cattle Contagious Diseases Act of 1905");

(K) the matter under the heading "Bureau of Animal Industry" of the Act of June 30, 1914 (38 Stat. 419, chapter 131; 21 U.S.C. 128);

(L) section 101 of Public Law 92-73 (21 U.S.C. 129);

(M) the matter under the heading "Miscellaneous" of the Act of May 26, 1910 (36 Stat. 440, chapter 256; 21 U.S.C. 131);

(N) sections 1 through 6 and 11 through 13 of Public Law 87-518 (21 U.S.C. 134-134h); or

(O) any other Act administered by the Secretary relating to plant or animal diseases or pests, other than the first section of Public Law 91-239 (21 U.S.C. 135).

(2) Customs territory

For the purposes of subsection (a) of this section, the term "customs territory of the United States" means the 50 States, the District of Columbia, and Puerto Rico.

(3) Person

For the purposes of this section, the term "person" means an individual, corporation, partnership, trust, association, or any other public or private entity, or any officer, employee, or agent thereof.

(4) United States

For the purposes of subsection (b) of this section, the term "United States" means the several States of the United States, the District of Columbia, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

(5) Vessel

For the purposes of subsection (a) of this section, the term "vessel" does not include any ferry.

(Pub. L. 101-624, title XXV, § 2509, Nov. 28, 1990, 104 Stat. 4069; Pub. L. 101-508, title I, § 1203, Nov. 5, 1990, 104 Stat. 1388-11; Pub. L. 102-237, title X, § 1015, Dec. 13, 1991, 105 Stat. 1902.)

REFERENCES IN TEXT

Section 101 of Public Law 92-73, referred to in subsec. (f)(1)(L), is listed in a Similar Provisions note set out under section 129 of this title.

CODIFICATION

Section is comprised of section 2509 of Pub. L. 101-624. Subsecs. (b) and (c)(2) of section 2509 of Pub. L. 101-624 amended section 147a(f) of Title 7, Agriculture, and section 114a of this title, respectively.

AMENDMENTS

1991—Subsec. (a)(1). Pub. L. 102-237, § 1015(1), designated existing provisions as subpar. (A), realigned margin, added heading, and added subpars. (B) to (D).

Subsec. (a)(3)(B)(ii). Pub. L. 102-237, § 1015(2), added cl. (ii) and struck out former cl. (ii) which read as follows: "The Secretary of Treasury shall use the Account to provide reimbursements to any appropriations accounts that incur the costs associated with the services authorized in paragraph (1). Any such reimbursement shall be subject to appropriations under clause (v)."

Subsec. (a)(4). Pub. L. 102-237, § 1015(3), substituted "Subject to the limits set forth in paragraph (1), the" for "The".

1990—Subsec. (a)(1). Pub. L. 101-508, § 1203(1), substituted "an international passenger, commercial vessel, commercial aircraft, commercial truck, or railroad car." for "a commercial vessel, commercial aircraft, commercial truck, or railroad car,".

Subsec. (a)(3)(B)(ii). Pub. L. 101-508, § 1203(2)(A), inserted at end "Any such reimbursement shall be subject to appropriations under clause (v)."

Subsec. (a)(3)(B)(v). Pub. L. 101-508, § 1203(2)(B), added cl. (v).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-508 effective Nov. 29, 1990, see section 1301 of Pub. L. 101-508, set out as a note under section 511r of Title 7, Agriculture.

CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

SUBCHAPTER IV—FOOD

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in sections 453, 457, 466, 467, 467f, 601, 607, 620, 679, 802, 811, 829, 902, 1033, 1049, 1052, 1401, 1402, 1403 of this title; title 7 sections 136v, 1381, 1431c, 5341, 6519; title 15 sections 70j, 1261, 1263, 1277, 1457, 1459, 1460, 2057a, 2057b, 2079; title 18 section 42; title 26 sections 170, 4817; title 35 sections 155, 156, 271; title 42 sections 262, 300aa-22, 300aa-23, 1396r-8, 1786, 3512, 7671.

SUBCHAPTER I—SHORT TITLE

§ 301. Short title

SHORT TITLE OF 1992 AMENDMENTS

Pub. L. 102-571, title I, § 101(a), Oct. 29, 1992, 106 Stat. 4491, provided that: "This title [enacting sections 379g and 379h of this title, transferring sections 372a, 376, and 379c of this title to sections 376, 379e and 379f, respectively, of this title, amending sections 321, 331, 342, 343, 346a, 351, 352, 360j, 361, 362, 453, 601, and 1033 of this title, enacting provisions set out as notes under section 379g of this title, and amending provisions set out as notes under sections 343 and 343-1 of this title] may be cited as the 'Prescription Drug User Fee Act of 1992'."

Pub. L. 102-571, title II, § 201, Oct. 29, 1992, 106 Stat. 4500, provided that: "This title [enacting provisions set out as notes under sections 343 and 393 of this title and amending provisions set out as notes under sections 343 and 343-1 of this title] may be cited as the 'Dietary Supplement Act of 1992'."

Pub. L. 102-353, § 1(a), Aug. 26, 1992, 106 Stat. 941, provided that: "This Act [amending sections 333, 353, and 381 of this title and enacting provisions set out as a note under section 353 of this title] may be cited as the 'Prescription Drug Amendments of 1992'."

Pub. L. 102-300, § 1(a), June 16, 1992, 106 Stat. 238, provided that: "This Act [amending sections 321, 331, 334, 346a, 352, 353, 356, 357, 360c, 360d, 360g to 360l, 360*l*, 360mm, 371 to 372a, 376, and 381 of this title and section 262 of Title 42, The Public Health and Welfare and enacting and amending provisions set out as notes under section 360l of this title] may be cited as the 'Medical Device Amendments of 1992'."

Pub. L. 102-282, § 1(a), May 13, 1992, 106 Stat. 149, provided that: "This Act [enacting sections 335a to 335c of this title, amending sections 321, 336, 337, and 355 of this title, and enacting provisions set out as notes under section 335a of this title] may be cited as the 'Generic Drug Enforcement Act of 1992'."

SHORT TITLE OF 1990 AMENDMENTS

Pub. L. 101-635, § 1(a), Nov. 28, 1990, 104 Stat. 4583, provided that: "This Act [enacting sections 379b to 379d and 394 of this title] may be cited as the 'Food and Drug Administration Revitalization Act'."

Pub. L. 101-629, § 1(a), Nov. 28, 1990, 104 Stat. 4511, provided that: "This Act [enacting sections 360*l* and 383 of this title, amending sections 321, 333, 351, 353, and 360c to 360j of this title and sections 263b to 263n of Title 42, The Public Health and Welfare, redesignating sections 263b to 263n of Title 42 as sections 360gg to 360ss of this title, repealing section 263b of Title 42, and enacting provisions set out as notes under sections 333, 360c, 360l, 360j, 360hh and 383 of this title] may be cited as the 'Safe Medical Devices Act of 1990'."

Pub. L. 101-535, § 1(a), Nov. 8, 1990, 104 Stat. 2353, provided that: "This Act [enacting section 343-1 of this title, amending sections 321, 337, 343, 345, and 371 of this title, and enacting provisions set out as notes under sections 343 and 343-1 of this title] may be cited as the 'Nutrition Labeling and Education Act of 1990'."

SHORT TITLE OF 1968 AMENDMENTS

Pub. L. 90-602, § 1, Oct. 18, 1968, 82 Stat. 1173, provided that: "This Act [enacting provisions now comprising part C (§§ 360gg-360ss) of subchapter III of this chapter and provisions set out as notes under section 360hh of this title] may be cited as the 'Radiation Control for Health and Safety Act of 1968'."

SUBCHAPTER II—DEFINITIONS

§ 321. Definitions; generally

For the purposes of this chapter—

[*See main edition for text of (a) to (f)*]

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[*See main edition for text of (2)*]

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

[*See main edition for text of (1) to (3)*]

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[*See main edition for text of (i) to (t)*]

(u) The term "safe" as used in paragraph (s) of this section and in sections 348, 360b, and 379e of this title, has reference to the health of man or animal.

[*See main edition for text of (v) to (x)*]

(y) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

[*See main edition for text of (2) to (6); (z) and (aa)*]

(bb) The term "abbreviated drug application" means an application submitted under section 355(j) or 357 of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 335a of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 335b and 335c of this title, includes any supplement to such an application.

(cc) The term "knowingly" or "knew" means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(dd) For purposes of section 335a of this title, the term "high managerial agent"—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product:

(ee) For purposes of sections 335a and 335b of this title, the term "drug product" means a drug subject to regulation under section 355, 357, 360b, or 382 of this title or under section 262 of title 42.

(ff) The term "Commissioner" means the Commissioner of Food and Drugs.

(As amended Nov. 8, 1990, Pub. L. 101-535, § 5(b), 104 Stat. 2362; Nov. 28, 1990, Pub. L. 101-629, § 16(b), 104 Stat. 4526; May 13, 1992, Pub. L. 102-282, § 6, 106 Stat. 161; June 16, 1992, Pub. L. 102-300, § 6(a), (b), 106 Stat. 240; Oct. 29, 1992, Pub. L. 102-571, title I, § 107(1), 106 Stat. 4499.)

AMENDMENT OF PARAGRAPH (g)(1)

Pub. L. 101-535, §§ 5(b), 10(a), Nov. 8, 1990, 104 Stat. 2362, 2365, provided that, effective six months after the date of promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with certain exceptions, paragraph (g)(1) of this section is amended by inserting at the end "A food for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug under clause (B) solely because the label or labeling contains such a claim."

AMENDMENTS

1992—Pars. (c), (d). Pub. L. 102-300, § 6(b)(1), which directed the substitution of "Health and Human Services" for "Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. Previously, references to the Department and Secretary of Health and Human Services were substituted for references to the Department and Secretary of Agriculture pursuant to the provisions cited in the Change of Name and Transfer of Functions notes set out below.

Par. (h). Pub. L. 102-300, § 6(a)(1), substituted "its primary" for "any of its principal" in two places.

Par. (u). Pub. L. 102-571 substituted "379e" for "376".

Par. (y)(1). Pub. L. 102-300, § 6(b)(2), struck out "of Health, Education, and Welfare" after "employees of the Department".

Pars. (bb) to (ee). Pub. L. 102-282 added pars. (bb) to (ee).

Par. (ff). Pub. L. 102-300, § 6(a)(2), added par. (ff).

1990—Par. (g)(1). Pub. L. 101-829, § 16(b)(1), struck out before period at end "; but does not include devices or their components, parts, or accessories".

Par. (h)(3). Pub. L. 101-629, § 16(b)(2), which directed the amendment of subpar. (3) by substituting "its primary" for "any of its principal", could not be executed because "any of its principal" did not appear in subpar. (3).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101-535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 102-282

Amendment by Pub. L. 102-282 not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102-282, see section 7 of Pub. L. 102-282, set out as a note under section 335a of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 346b, 350, 352, 355, 360b, 379e, 802, 825 of this title; title 7 section 136; title 15 sections 1454, 1456, 1471, 2052, 2602; title 18 sections 842, 1365; title 35 section 156; title 42 sections 274e, 300cc-12, 1396r-8; title 49 App. section 2802.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in section 378 of this title; title 15 section 1456.

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

[*See main edition for text of (a) to (d)*]

(e) The refusal to permit access to or copying of any record as required by section 350a or 373 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 355(i) or (k), 357(d) or (g), 360b(j), (*l*), or (m), 360e(f), or 360i of this title, or the refusal to permit access to or verification or copying of any such required record.

[*See main edition for text of (f) to (h)*]

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344, 356, 357, or 379e of this title.

[*See main edition for text of (2) and (3)*]

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information ac-

quired under authority of section 344, 348, 350a, 355, 356, 357, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 374, 379e, or 379 of this title concerning any method or process which as a trade secret is entitled to protection. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

[*See main edition for text of (k) to (p)*]

(q)(1) The failure or refusal to (A) comply with any requirement prescribed under section 360h or 360j(g) of this title, (B) furnish any notification or other material or information required by or under section 360i or 360j(g) of this title, or (C) comply with a requirement under section 360*l* of this title.

[*See main edition for text of (2); (r) to (t)*]

(As amended Nov. 3, 1990, Pub. L. 101-502, § 5(j), 104 Stat. 1289; Nov. 5, 1990, Pub. L. 101-508, title IV, § 4755(c)(2), 104 Stat. 1388-210; June 16, 1992, Pub. L. 102-300, § 3(a)(1), 106 Stat. 238; Oct. 29, 1992, Pub. L. 102-571, title I, § 107(2), (3), 106 Stat. 4499.)

AMENDMENTS

1992—Pars. (i)(1), (j). Pub. L. 102-571 substituted "379e" for "376".

Par. (q)(1)(C). Pub. L. 102-300 added cl. (C).

1990—Par. (e). Pub. L. 101-502 substituted "or (k)" for "or (j)".

Par. (j). Pub. L. 101-508 inserted at end "This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee."

EFFECTIVE DATE OF 1990 AMENDMENT

Section 4755(c)(2) of Pub. L. 101-508 provided that the amendment made by that section is effective as if included in subtitle D of title VI of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239, title VI, §§ 6601, 6602, Dec. 19, 1989, 103 Stat. 2285, see 42 U.S.C. 300aa-1 note, 300aa-10 note.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 332, 333, 347b, 360i, 360j of this title; title 42 section 1396r-8.

§ 332. Injunction proceedings

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 360j of this title; title 42 section 1396r-8.

§ 333. Penalties

[*See main edition for text of (a)*]

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title,

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

[*See main edition for text of (2) and (3)*]

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

[*See main edition for text of (ii)*]

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith,

unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a bateh certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a gnaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) nor 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving mishranded food

No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 331 of this title involving misbranded food if the violation exists solely because the food is misbranded under section 343(a)(2) of this title because of its advertising.

(e) [2] Prohibited distribution of anabolic steroids

(1) Except as provided in paragraph (2), any person who distributes or possesses with the intent to distribute any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than three years or fined under title 18, or both.

(2) Any person who distributes or possesses with the intent to distribute to an individual under 18 years of age, any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than six years or fined under title 18, or both.

(e) [2] Prohibited distribution of human growth bormone

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act [21 U.S.C. 801 et seq.] for the purposes of forfeiture under section 413 of such Act [21 U.S.C. 853].

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f) Violations related to devices

(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 360i(a) or 360j(f) of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public heaith,

(ii) to any person who commits minor violations of section 360i(e) or 360i(f) of this title (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 351(a)(2)(A) of this title which involve one or more devices which are not defective.

(2)(A) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after opportunlty for a

[2] So in original. Two subsecs. (e) have been enacted.

hearing provided in accordance with this subparagraph and section 554 of title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested, in accordance with paragraph (2)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(As amended Nov. 28, 1990, Pub. L. 101-629, § 17(a), 104 Stat. 4526; Nov. 29, 1990, Pub. L. 101-647, title XIX, § 1904, 104 Stat. 4853; Aug. 26, 1992, Pub. L. 102-353, § 3, 106 Stat. 941.)

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (e)(3), is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, as amended, which is classified principally to subchapter I (§ 801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

1992—Subsec. (b)(1). Pub. L. 102-353, § 3(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title because of an importation of a drug in violation of section 381(d)(1) of this title, because of a sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, because of the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, or the distribution of drugs in violation of section 353(e)(2)(A) of this title shall be imprisoned for not more than 10 years or fined not more than $250,000, or both."

Subsec. (b)(4)(A). Pub. L. 102-353, § 3(b)(1), substituted "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (b)(4)(B)(i). Pub. L. 102-353, § 3(b)(1), (2), substituted "before the institution of a criminal proceeding against" for "before the arrest of" and "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (b)(5). Pub. L. 102-353, § 3(b)(3), substituted "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (c). Pub. L. 102-353, § 3(b)(4), substituted "subsection (a)(1) of this section" for "subsection (a) of this section".

Subsec. (d). Pub. L. 102-353, § 3(b)(4), (5), substituted "subsection (a)(1) of this section" for "subsection (a) of this section" and struck out ", and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead" after "advertising".

1990—Subsec. (e). Pub. L. 101-647 added subsec. (e) relating to human growth hormone.

Subsec. (f). Pub. L. 101-629 added subsec. (f).

EFFECTIVE DATE OF 1990 AMENDMENT

Section 17(b) of Pub. L. 101-629 provided that:

"(b) EFFECTIVE DATE OF APPLICATION TO DEVICE USER FACILITIES.—

"(1) The Secretary of Health and Human Services shall conduct a study to determine whether there has been substantial compliance with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)] by device user facilities (as defined in section 519(b)(5)(A) of such Act). The Secretary shall report the results of the study to the Congress after the expiration of 45 months after the date of the enactment of this Act [Nov. 28, 1990].

"(2)(A) If upon the expiration of 48 months after the date of the enactment of this Act the Secretary has not made the report required by paragraph (1), section 303(f) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 333(f)], as added by the amendment made by subsection (a), shall take effect with respect to device user facilities (as defined in section 519(b)(5)(A) of such Act).

"(B) If in the report under paragraph (1) the Secretary reports that there has been substantial compliance with the requirements of such section 519(b) by a type of device user facility and if the Secretary does not make a determination under subparagraph (C) with respect to such type of facility, such section 303(f) shall not take effect with respect to such type of facility.

"(C) If the Secretary determines in the report under paragraph (1) that there is not substantial compliance with the requirements of such section 519(b) by a type of device user facility or if the Secretary makes such a determination after making the report under paragraph (1), such section 303(f) shall

take effect with respect to such type of facility upon the effective date of the report."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 346a, 360j, 859 of this title; title 15 section 1456.

§ 333a. Repealed. Pub. L. 101-647, title XIX, § 1905, Nov. 29, 1990, 104 Stat. 4853

Section, Pub. L. 100-690, title II, § 2401, Nov. 18, 1988, 102 Stat. 4230, related to forfeiture and illegal trafficking in steroids or human growth hormones.

§ 334. Seizure

[*See main edition for text of* (a) *to* (c)]

(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures

(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter, under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 381(e) of this title can and will be met: *Provided, however*, That the provisions of this sentence shall not apply where condemnation is based upon violation of section 342(a)(1), (2), or (6), section 351(a)(3), section 352(j), or section 361(a) or (d) of this title: *And provided further*, That where such exportation is made to the original foreign supplier, then paragraphs (1) and (2) of section 381(e) of this title and the foregoing proviso shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381(e) of this title have been met. Any article condemned by reason of its being an article which may not, under section 344 or 355 of this title, be introduced into interstate commerce, shall be disposed of by destruction.

[*See main edition for text of* (2) *and* (3); (e) *to* (g)]

(As amended June 16, 1992, Pub. L. 102-300, § 6(c), 106 Stat. 240.)

AMENDMENTS

1992—Subsec. (d)(1). Pub. L. 102-300 substituted "381(e)" for "381(d)" in three places and "paragraphs" for "clauses" before "(1) and (2) of section 381(e)".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360j, 372 of this title; title 42 section 1396r-8.

§ 335a. Debarment, temporary denial of approval, and suspension

(a) Mandatory debarment

(1) Corporations, partnerships, and associations

If the Secretary finds that a person other than an individual has been convicted, after May 13, 1992, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

(2) Individuals

If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct—

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this chapter,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

(h) Permissive debarment

(1) In general

The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2), debar—

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application, or

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application.

(2) Persons subject to permissive debarment

The following persons are subject to debarment under paragraph (1):

(A) Corporations, partnerships, and associations

Any person other than an individual that the Secretary finds has been convicted—

(i) for conduct that—

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before May 13, 1992), a misdemeanor under Federal law, or a felony under State law, or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1) of this section,

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(B) Individuals

(i) Any individual whom the Secretary finds has been convicted of—

(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this chapter, or

(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2) of this section,

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(ii) Any individual whom the Secretary finds has been convicted of—

(I) a felony which is not described in subsection (a)(2) of this section or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

(II) a conspiracy to commit, or aiding or abetting, such felony,

if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) of this section or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a patteru of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iv) Any high managerial agent whom the Secretary finds—

(I) worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment under subsection (a)(2) of this section, or clause (i), of such other individual,

(II) had actual knowledge of the actions described in subclause (I) of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge,

(III) knew that the actions described in subclause (I) were violative of law, and

(IV) did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions,

if the Secretary finds that the type of conduct which served as the basis for such other individual's conviction undermines the process for the regulation of drugs.

(3) Stay of certain orders

An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

(c) Debarment period and considerations

(1) Effect of debarment

The Secretary—

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) of this section during the period such person is debarred,

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B) of this section, debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

(C) shall, if the Secretary makes the finding described in paragraph (6) or (7) of section 335b(a) of this title, assess a civil penalty in accordance with section 335b of this title.

(2) Debarment periods

(A) In general

The Secretary shall debar a person under subsection (a) or (b) of this section for the following periods:

(i) The period of debarment of a person (other than an individual) under subsection (a)(1) of this section shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) of this section occurs within 10 years after such person has been debarred under subsection (a)(1) of

this section, the period of debarment shall be permanent.

(ii) The debarment of an individual under subsection (a)(2) of this section shall be permanent.

(iii) The period of debarment of any person under subsection (b)(2) of this section shall not be more than 5 years.

The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

(B) Notification

Upon a conviction for an offense described in subsection (a) or (b) of this section or upon execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify the Secretary that the person acquiesces to debarment and such person's debarment shall commence upon such notification.

(3) Considerations

In determining the appropriateness and the period of a debarment of a person under subsection (b) of this section and any period of debarment beyond the minimum specified in subparagraph (A)(i) of paragraph (2), the Secretary shall consider where applicable—

(A) the nature and seriousness of any offense involved,

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this chapter or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

(d) Termination of debarment

(1) Application

Any person that is debarred under subsection (a) of this section (other than a person permanently debarred) or any person that is debarred under subsection (b) of this section may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(2) Deadline

The Secretary shall grant or deny any application respecting a debarment which is submitted under paragraph (1) within 180 days of the date the application is submitted.

(3) Action by the Secretary

(A) Corporations

(i) Conviction reversal

If the conviction which served as the basis for the debarment of a person under subsection (a)(1) or (b)(2)(A) of this section is reversed, the Secretary shall withdraw the order of debarment.

(ii) Application

Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that—

(I) changes in ownership, management, or operations have fully corrected the causes of the offense involved and provide reasonable assurances that the offense will not occur in the future, and

(II) sufficient audits, conducted by the Food and Drug Administration or by independent experts acceptable to the Food and Drug Administration, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements.

In the case of persons debarred under subsection (a)(1) of this section, such termination shall take effect no earlier than the expiration of one year from the date of the debarment.

(B) Individuals

(i) Conviction reversal

If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) of this section or clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) of this section is reversed, the Secretary shall withdraw the order of debarment.

(ii) Application

Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) of this section if such termination serves the interests of justice and adequately protects the integrity of the drug approval process.

(4) Special termination

(A) Application

Any person that is debarred under subsection (a)(1) of this section (other than a person permanently debarred under subsection (c)(2)(A)(i) of this section) or any individual who is debarred under subsection (a)(2) of this section may apply to the Secretary for special termination of deharment under this subsection. Any information submitted to the Secretary under this subparagraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(B) Corporations

Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that—

(i) the person making the application under subparagraph (A) has demonstrated that the felony conviction which was the basis for such person's debarment involved the commission of an offense which was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the hoard's or agent's office or employment,

(ii) all individuals who were involved in the commission of the offense or who knew or should have known of the offeuse have been removed from employment involving the development or approval of any drug subject to sections 355 or 357 of this title,

(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities, and

(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

(C) Individuals

Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that such individual has provided substantial assistance in the investigations or prosecutions of offenses which are described in subsection (a) or (b) of this section or which relate to any matter under the jurisdiction of the Food and Drug Administration.

(D) Secretarial action

The action referred to in subparagraphs (B) and (C) is—

(i) in the case of a person other than an individual—

(I) terminating the debarment immediately, or

(II) limiting the period of debarment to less than one year, and

(ii) in the case of an individual, limiting the period of debarment to less than permanent but to no less than 1 year,

whichever best serves the interest of justice and protects the integrity of the drug approval process.

(e) Publication and list of debarred persons

The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b) of this section, the effective date of the debarment, and the period of the debarment. The Secretary shall aiso maintain and make avallable to the public a list, updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such debarments, and of the termination of debarments.

(f) Temporary denial of approvai

(1) In general

The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (3), refuse by order, for the period prescribed by paragraph (2), to approve any abbreviated drug application submitted by any person—

(A) if such person is under an active Federal criminal investigation in counection with an action described in subparagraph (B),

(B) if the Secretary finds that such person—

(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services or to any other Federal, State, or local official in connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, such actions, or

(ii) has knowingly made or caused to be made a pattern or practice of false statements or misrepresentations with respect to material facts relating to any abbreviated drug application, or the production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of the Department of Health and Human Services, or has conspired to commit, or alded or abetted, such actions, and

(C) if a significant question has been raised regarding—

(i) the integrity of the approval process with respect to such abbreviated drug application, or

(ii) the reliablity of data in or concerning such person's abbreviated drug application.

Such an order may be modified or terminated at any time.

(2) Applicable period

(A) In general

Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate such denial—

(i) if the investigation with respect to which the finding was made does not result in a criminal charge against such person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered, or

(ii) if the Secretary determines that such finding was in error.

(B) Extension

If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in subparagraph (B) of paragraph (1), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate such extension if the charges have been dismissed, if a judgment of acquittal has been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

(3) Informal hearing

Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide such person with an opportunity for an informal hearing, to be held within such 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which such hearing is held, the Secretary shall notify the person given such hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. Such notification shall be final agency action.

(g) Suspension authority

(1) In general

If—

(A) the Secretary finds—

(i) that a person has engaged in conduct described in subparagraph (B) of subsection (f)(1) of this section in connection with 2 or more drugs under abbreviated drug applications, or

(ii) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of one or more drugs approved under an abbreviated drug application during a 2-year period, and—

(I) such violations may undermine the safety and efficacy of such drugs, and

(II) the causes of such violations have not been corrected within a reasonable period of time following notice of such violations by the Secretary, and

(B) such person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in subparagraph (A),

the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to such conduct described in subparagraph (A) or suspending the distribution of all drugs approved under abbreviated drug applications of such person if the Secretary finds that such conduct may have affected the development or approval of a significant number of drugs which the Secretary is unable to identify. The Secretary shall exclude a drug from such order if the Secretary determines that such conduct was not likely to have influenced the safety or efficacy of such drug.

(2) Public health waiver

The Secretary shall, on the Secretary's own initiative or in response to a petition, walve the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)) with respect to any drug if the Secretary finds that such walver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available. The Secretary shall act on any petition seeking action under this paragraph within 180 days of the date the petition is submitted to the Secretary.

(h) Termination of suspension

The Secretary shall withdraw an order of suspension of the distribution of a drug under subseetion (g) of this section if the person with respect to whom the order was issued demonstrates in a petition to the Secretary—

(1)(A) on the basis of an audit by the Food and Drug Administration or by experts acceptable to the Food and Drug Administration, or on the basis of other information, that the development, approval, manufacturing, and distribution of such drug is in substantial compliance with the applicable requirements of this chapter, and

(B) changes in ownership, management, or operations—

(i) fully remedy the patterns or practices with respect to which the order was issued, and

(ii) provide reasonable assurances that such actions will not occur in the future, or

(2) the initial determination was in error.

The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding. Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

(i) Procedure

The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) of this section with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(j) Judicial review

(1) In general

Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(2) Exception

Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) of this section may obtain a review of such decision by the Unlted States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by filing in such court (within 30 days following the date the person is notified of the Secretary's decision) a complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

(k) Certification

Any application for approval of a drug product shall include—

(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) of this section, in connection with such application, and

(2) if such application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) of this section which occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of such application.

(*l*) Applicability

(1) Conviction

For purposes of this section, a person is considered to have been convicted of a criminal offense—

(A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending,

(B) when a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court, or

(C) when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld.

(2) Effective dates

Subsection (a) of this section, subparagraph (A) of subsection (b)(2) of this section, and clauses (i) and (ii) of subsection (b)(2)(B) of this section shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b) of this section. Clauses (iii) and (iv) of subsection (b)(2)(B) of this section and subsections (f) and (g) of this section shall not apply to an act or action which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g) of this section. Clause (iv) of subsection (b)(2)(B) of this section shall not apply to an action which occurred before June 1, 1992. Subsection (k) of this section shall not apply to applications submitted to the Secretary before June 1, 1992.

(June 25, 1938, ch. 675, § 306, as added May 13, 1992, Pub. L. 102-282, § 2, 106 Stat. 150.)

PRIOR PROVISIONS

A prior section 306 of act June 25, 1938, was renumbered section 309 and is classified to section 336 of this title.

CONSTRUCTION

Section 7 of Pub. L. 102-282 provided that: "No amendment made by this Act [enacting this section and sections 335b and 335c of this title and amending sections 321, 336, 337, and 355 of this title] shall preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by this Act."

CONGRESSIONAL FINDINGS

Section 1(c) of Pub. L. 102-282 provided that: "The Congress finds that—

"(1) there is substantial evidence that significant corruption occurred in the Food and Drug Administration's process of approving drugs under abbreviated drug applications,

"(2) there is a need to establish procedures designed to restore and to ensure the integrity of the abbreviated drug application approval process and to protect the public health, and

"(3) there is a need to establish procedures to bar individuals who have been convicted of crimes pertaining to the regulation of drug products from working for companies that manufacture or distribute such products."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 335b of this title.

§ 335b. Civil penalties

(a) In general

Any person that the Secretary finds—

(1) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a ma-

terial fact in connection with an abbreviated drug application,

(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

(3) destroyed, altered, removed, or secreted, or procured the destrnction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application,

(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug applicatlon,

(6) is a person that has an approved or pending drug product application and has knowingly—

(A) employed or retained as a consultant or contractor, or

(B) otherwise used in any capacity the services of,

a person who was debarred under sectlon 335a of this title, or

(7) is an individual debarred under section 335a of this title and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product applicatlon,

shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

(b) Procedure

(1) In general

(A) Action by the Secretary

A civil penalty under subsection (a) of this section shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) Action by the Attorney General

In lieu of a proceeding under subparagraph (A), the Attorney General may, upon request of the Secretary, institute a civil action to recover a civil money penalty in the amount and for any of the acts set forth in subsection (a) of this section. Such an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated by the Attorney General under this chapter.

(2) Amount

In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

(3) Limitation on actions

No action may be initiated under this section—

(A) with respect to any act described in subsection (a) of this section that occurred before May 13, 1992, or

(B) more than 6 years after the date when facts material to the act are known or reasonably should have been known by the Secretary but in no event more than 10 years after the date the act took place.

(c) Judicial review

Any person that is the subject of an adverse decision under subsection (b)(1)(A) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(d) Recovery of penalties

The Attorney General may recover any civil penalty (plus interest at the currently prevalling rates from the date the penalty became final) assessed under subsection (b)(1)(A) of this sectlon in an action brought in the name of the United States. The amount of such penalty may be deducted, when the penalty has become final, from any sums then or later owing by the United States to the person against whom the penalty has been assessed. In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

(e) Informants

The Secretary may award to any individual (other than an officer or employee of the Federal Government or a person who materially participated in any conduct described in subsection (a) of this section) who provides informatlon leading to the imposition of a civil penalty under this section an amount not to exceed—

(1) $250,000, or

(2) one-half of the penalty so imposed and collected,

whichever is less. The decision of the Secretary on such award shall not be reviewable.

(June 25, 1938, ch. 675, § 307, as added May 13, 1992, Pub. L. 102-282, § 3, 106 Stat. 159.)

CODIFICATION

May 13, 1992, referred to in subsec. (b)(3)(A), was in the original "the date of the enactment of this Act", which was translated as meaning the date of enactment of Pub. L. 102-282, which enacted this section, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 307 of act June 25, 1938, was renumbered section 310 and is classified to section 337 of this title.

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102-282, see section 7 of Pub. L. 102-282, set out as a note under section 335a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 335a of this title.

§ 335c. Authority to withdraw approval of abhreviated drug applications

(a) In general

The Secretary—

(1) shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or material false statement, and

(2) may withdraw approval of an abbreviated drug application if the Secretary finds that the applicant has repeatedly demonstrated a lack of abillty to produce the drug for which the application was submitted in accordance with the formuiations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce.

(b) Procedure

The Secretary may not take any action under subsection (a) of this section with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(c) Applicability

Subsection (a) of this section shall apply with respect to offenses or acts regardless of when such offenses or acts occurred.

(d) Judicial review

Any person that is the subject of an adverse decision under subsection (a) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(June 25, 1938, ch. 675, § 308, as added May 13, 1992, Pub. L. 102-282, § 4, 106 Stat. 160.)

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102-282, see section 7 of Pub. L. 102-282, set out as a note under section 335a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title.

§ 336. Report of minor violations

[*See main edition for text*]

(June 25, 1938, ch. 675, § 309, formerly § 306, 52 Stat. 1045; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; renumbered § 309, May 13, 1992, Pub. L. 102-282, § 2, 106 Stat. 150.)

§ 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State nay bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforeement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

(June 25, 1938, ch. 675, § 310, formerly § 307, 52 Stat. 1046; Sept. 3, 1954, ch. 1263, § 37, 68 Stat. 1239; Nov. 8, 1990, Pub. L. 101-535, § 4, 104 Stat.

2362; renumbered § 310, May 13, 1992, Pub. L. 102-282, § 2, 106 Stat. 150.)

AMENDMENTS

1990—Pub. L. 101-535 substituted "(a) Except as provided in subsection (b) of this section, all" for "All" and "any proceeding under this section" for "any such proceeding" and added subsec. (b).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective 24 months after Nov. 8, 1990, except that such amendment effective Dec. 31, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, see section 10(a)(1)(C) of Pub. L. 101-535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

SUBCHAPTER IV—FOOD

§ 341. Definitions and standards for food

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 337, 343, 343-1, 350, 371 of this title.

§ 342. Adulterated food

A food shall be deemed to be adulterated—

[*See main edition for text of* (a) *and* (b)]

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

[*See main edition for text of* (d) *and* (e)]

(As amended Oct. 29, 1992, Pub. L. 102-571, title I, § 107(4), 106 Stat. 4499.)

AMENDMENTS

1992—Par. (c). Pub. L. 102-571 substituted "379e(a)" for "376(a)".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 346, 346a, 346b, 347b, 348, 350a, 360b, 379e of this title.

§ 343. Misbranded food

A food shall be deemed to be misbranded—

[*See main edition for text of* (a) *to* (d)]

(e) Package form

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

[*See main edition for text of* (f) *to* (h)]

(i) Label where no representation as to definition and standard of identity

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided,* That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

[*See main edition for text of* (j)]

(k) Artificial flavoring, artificial coloring, or chemical preservatives

If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided,* That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

[*See main edition for text of* (l)]

(m) Color additives

If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title.

[*See main edition for text of* (n)]

(o) Saccharin for immediate consumption

(1) If it contains saccharin, unless, except as provided in subparagraph (2), its label and labeling bear the following statement: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS". Such statement shall be located in a conspicuous place on such label and labeling as proximate as possible to the name of such food and shall appear in conspicuous and legible type in contrast by typography, layout,

and color with other printed matter on such label and labeling.

(2) The Secretary may by regulation review and revise or remove the requirement of subparagraph (1) if the Secretary determines such action is necessary to reflect the current state of knowledge concerning saccharin.

(p) Saccharin not for immediate consumption

(1) If it contains saccharin and is offered for sale, but not for immediate consumption, at a retail establishment, unless such retail establishment displays prominently, where such food is held for sale, notice (provided by the manufacturer of such food pursuant to subparagraph (2) for consumers respecting the information required by paragraph (o) to be on food labels and labeling.

(2) Each manufacturer of food which contains saccharin and which is offered for sale by retail establishments but not for immediate consumption shall, in accordance with regulations promulgated by the Secretary pursuant to subparagraph (4), take such action as may be necessary to provide such retail establishments with the notice required by subparagraph (1).

(3) The Secretary may by regulation review and revise or remove the requirement of subparagraph (1) if he determines such action is necessary to reflect the current state of knowledge concerning saccharin.

(4) The Secretary shall by regulation prescribe the form, text, and manner of display of the notice required by subparagraph (1) and such other matters as may be required for the implementation of the requirements of that subparagraph and subparagraph (2). Regulations of the Secretary under this subparagraph shall be promulgated after an oral hearing but without regard to the National Environmental Policy Act of 1969 [42 U.S.C. 4321 et seq.] and chapter 5 of title 5. In any action brought for judicial review of any such regulation, the reviewing court may not postpone the effective date of such regulation.

(q) Nutrition information

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this chapter before October 1, 1990, if the Secretary detormines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

(2)(A) If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

(B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (D).

(B)(i) Upon the expiration of 12 months after November 8, 1990, the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subparagraphs (1) and (2). Such guldelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply—

(I) in the case of raw agricnltural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after November 8, 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

(C)(i) Upon the expiration of 30 months after November 8, 1990, the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.

(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).

(iii) Regulations issued under subclause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

(E) For purposes of this subparagraph, the term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

(iii) which is an infant formula subject to section 350a of this title,

(iv) which is a medical food as defined in section 360ee(b) of this title, or

(v) which is described in section 345(2) of this title.

(B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.

(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

(E) If a food to which section 350 of this title applies (as defined in section 350(c) of this title) contains one or more of the nutrients required by subparagraph (1) or (2) to be in the label or labeling of the food, the label or labeling of such food shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for such food and which is specified in regulations of the Secretary.

(F) Subparagraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally selis food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

(r) Nutrition levels and health-related claims

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which ls offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or 5(D).[1]

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)—

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless—

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basls of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which ls diet related unless—

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximlty to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See _____ for nutrition information.". In the statement—

(i) the blank shall identify the panel on whlch the information described in the statement may be found, and

(ii) if the Secretary determines that the food contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the statement shall also identify such nutrient.

(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

[1] So in original. Probably should be "(5)(D)."

(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (I) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term "diet" was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).

(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(ii) A regulation described in subclause (i) shall describe—

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and

(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in subelause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subelause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary denies the petition, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this subsection [2] and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 350a(h) of this title and medical foods as defined in section 360ee(b) of this title.

(B) Subelauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishinents in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 341 of this title shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and

[2] So in original. Probably should be "paragraph".

standard, respecting the validity of such claim, established by regulation of the Secretary.

(As amended Nov. 8, 1990, Pub. L. 101-535, §§ 2(a), 3(a), 7, 104 Stat. 2353, 2357, 2364; Aug. 17, 1991, Pub. L. 102-108, § 2(a), (c), 105 Stat. 549; Oct. 29, 1992, Pub. L. 102-571, title I, § 107(5), (6), 106 Stat. 4499.)

CODIFICATION

Pars. (e), (k), (o), and (p) of this section are set out in this supplement to correct error appearing in the main edition.

AMENDMENTS

1992—Par. (i). Pub. L. 102-571, § 107(5), substituted "379e(c)" for "376(c)".

Par. (m). Pub. L. 102-571, § 107(6), substituted "379e" for "376".

1991—Par. (i). Pub. L. 102-108, § 2(c), amended directory language of Pub. L. 101-535, § 7(1), (3). See 1990 Amendment note below.

Par. (q)(4)(A). Pub. L. 102-108, § 2(a), substituted "(D)" for "(C)".

1990—Par. (i). Pub. L. 101-535, § 7, as amended by Pub. L. 102-108, § 2(c), substituted "Unless" for "If it is not subject to the provisions of paragraph (g) unless", inserted "and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food", and substituted "colors not required to be certified under section 376(c) of this title" for "colorings" the first time appearing.

Par. (q). Pub. L. 101-535, § 2(a), added par. (q).

Par. (r). Pub. L. 101-535, § 3(a), added par. (r).

EFFECTIVE DATE OF 1990 AMENDMENT

Section 10(a) of Pub. L. 101-535, as amended by Pub. L. 102-571, title II, § 202(a)(3), Oct. 29, 1992, 106 Stat. 4501, provided that:

"(1) Except as provided in paragraph (2)—

"(A) the amendments made by section 2 [amending this section] shall take effect 6 months after—

"(i) the date of the promulgation of all final regulations required to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)], or

"(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations [Nov. 8, 1992, see 57 F.R. 56347],

except that section 403(q)(4) of such Act shall take effect as prescribed by such section,

"(B) the amendments made by section 3 [amending this section] shall take effect 6 months after—

"(i) the date of the promulgation of final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, or

"(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations [Nov. 8, 1992, see 57 F.R. 56347], except that any person marketing a food the brand name of which contains a term defined by the Secretary under section 403(r)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act shall be given an additional 6 months to comply with section 3,

"(C) the amendments made by section 4 [amending section 337 of this title] shall take effect 24 months after the date of the enactment of this Act [Nov. 8, 1990], except that such amendments shall take effect with respect to such dietary supplements [probably means dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, see section 202(a)(1) of Pub. L. 102-571, set out below] on December 31, 1993, and

"(D) the amendments made by section 5 [amending sections 321 and 345 of this title] shall take effect on the date the amendments made by section 3 take effect.

"(2) Section 403(q) of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 2 and section 403(r) of the Federal Food, Drug, and Cosmetic Act (as added by section 3) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 3.

"(3)(A) If the Secretary finds that a person who is subject to section 403(q)(4) of such Act is unable to comply with the requirements of such section upon the effective date of final regulations to implement section 403(q) of such Act or of proposed regulations to be considered as such final regulations because the Secretary has not made available to such person the information required by such section, the Secretary shall delay the application of such section to such person for such time as the Secretary may require to provide such information.

"(B) If the Secretary finds that compliance with section 403(q) or 403(r)(2) of such Act would cause an undue economic hardship, the Secretary may delay the application of such sections for no more than one year."

Section 10(c) of Pub. L. 101-535, as amended by Pub. L. 102-108, § 1, Aug. 17, 1991, 105 Stat. 549; Pub. L. 102-571, title I, § 107(17), Oct. 29, 1992, 106 Stat. 4500, provided that:

"(1) Except as provided in paragraphs (2) and (3), the amendments made by section 7 [amending this section] shall take effect one year after the date of the enactment of this Act [Nov. 8, 1990].

"(2)(A) If a food subject to section 403(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(g)] or a food with one or more colors required to be certified under section 721(c) [of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 379e(c)] bears a label which was printed before July 1, 1991, and which is attached to the food before May 8, 1993, such food shall not be subject to the amendments made by section 7(1) and section 7(3) [amending this section].

"(B) If a food described in subparagraph (A)—

"(i) bears a label which was printed after July 1, 1991, but before the date the proposed regulation described in clause (ii) takes effect as a final regulation and which was attached to the food before May 8, 1993, and

"(ii) meets the requirements of the proposed regulation of the Secretary of Health and Human Services published in 56 Fed. Reg. 28592-28636 (June 21, 1991) as it pertains to the amendments made by this Act [see Short Title of 1990 Amendment note set out under section 301 of this title],

such food shall not be subject to the amendments made by section 7(1) and section 7(3) [amending this section].

"(3) A food purported to be a beverage containing a vegetable or fruit juice which bears a label attached to the food before May 8, 1993, shall not be subject to the amendments made by section 7(2) [amending this section]."

REGULATIONS

Section 2(b) of Pub. L. 101-535, as amended by Pub. L. 102-571, title II, § 202(a)(2)(A), (B), Oct. 29, 1992, 106 Stat. 4500, 4501, provided that:

"(1) The Secretary of Health and Human Services shall issue proposed regulations to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)] within 12 months after the date of the enactment of this Act [Nov. 8, 1990], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final

regulations to implement the requirements of such section, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances..[sic] Such regulations shall—

"(A) require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet,

"(B) include regulations which establish standards, in accordance with paragraph (1)(A), to define serving size or other unit of measure for food,

"(C) permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

"(D) permit the nutrition information on the label or labeling of a food to remain the same or permit the information to be stated as a range even though (i) there are minor variations in the nutritional value of the food which occur in the normal course of the production or processing of the food, or (ii) the food is comprised of an assortment of similar foods which have variations in nutritional value.

"(2) If the Secretary of Health and Human Services does not promulgate final regulations under paragraph (1) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1) shall be considered as the final regulations upon the expiration of such 24 months, except that the proposed regulations applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not be considered to be final regulations until December 31, 1993. There shall be promptly published in the Federal Register notice of new status of the proposed regulations [see 57 F.R. 56347].

"(3) If the Secretary of Health and Human Services does not promulgate final regulations under section 403(q)(4) of the Federal Food, Drug, and Cosmetic Act upon the expiration of 6 months after the date on which the Secretary makes a finding that there has been no substantial compliance with section 403(q)(4)(C) of such Act, the proposed regulations issued in accordance with such section shall be considered as the final regulations upon the expiration of such 6 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations."

[Section 202(a)(2)(C) of Pub. L. 102-571 provided that: "The amendments made by subparagraph (B) [amending sections 2(b) and 3(b) of Pub. L. 101-535, set out above and below] shall not be construed to modify the effective date of final regulations under sections 2(b) and 3(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535] (21 U.S.C. 343 note) with respect to foods that are not such dietary supplements."]

Section 3(b) of Pub. L. 101-535, as amended by Pub. L. 102-571, title II, § 202(a)(2)(A), (B), Oct. 29, 1992, 106 Stat. 4500, 4501, provided that:

"(1)(A) Within 12 months of the date of the enactment of this Act [Nov. 8, 1990], the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(r)], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Such regulations—

"(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act,

"(ii) shall identify claims described in section 403(r)(1)(B) of such Act which comply with section 403(r)(3) of such Act,

"(iii) shall, in defining terms used to characterize the level of any nutrient in food under section 403(r)(2)(A)(i) of such Act, define—

"(I) free,

"(II) low,

"(III) light or lite,

"(IV) reduced,

"(V) less, and

"(VI) high,

unless the Secretary finds that the use of any such term would be misleading,

"(iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act,

"(v) shall provide that if multiple claims subject to section 403(r)(1)(A) of such Act are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy section 403(r)(2)(B) of such Act,

"(vi) shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(3) of such Act: Calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease,

"(vii) shall not require a person who proposes to make a claim described in section 403(r)(1)(B) of such Act which is in compliance with such regulations to secure the approval of the Secretary before making such claim,

"(viii) may permit a claim described in section 403(r)(1)(A) of such Act to be made for butter,

"(ix) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

"(x) shall establish, as required by section 403(r)(5)(D), the procedure and standard respecting the validity of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(5)(D) of such Act: folic acid and neural tube defects, antioxident [sic] vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

"(B) Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances..[sic]

"(2) If the Secretary does not promulgate final regulations under paragraph (1)(B) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1)(A) shall be considered as the final regulations upon the expiration of such 24 months, except that the proposed regulations applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substanees shall not be considered to be final regulations until December 31, 1993. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations [see 57 F.R. 56347]."

[For construction of amendment made by section 202(a)(2)(B) of Pub. L. 102-571 to section 3(b) of Pub. L. 101-535 set out above, see section 202(a)(2)(C) of Pub. L. 102-571 set out above following section 2(b) of Pub. L. 101-535.]

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Section 9 of Pub. L. 101-535 provided that: "The amendments made by this Act [enacting section 343-1 of this title and amending this section and sections

321, 337, 345, and 371 of this title] shall not be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], the Federal Meat Inspection Act [21 U.S.C. 601 et seq.], the Poultry Products Inspection Act [21 U.S.C. 451 et seq.], and the Egg Products Inspection Act [21 U.S.C. 1031 et seq.]."

PROHIBITION ON IMPLEMENTATION OF PUB. L. 101-535 WITH RESPECT TO DIETARY SUPPLEMENTS

Section 202(a)(1) of Pub. L. 102-571 provided that: "Notwithstanding any other provision of law and except as provided in subsection (b) [set out as a note below] and in the amendment made by paragraph (2)(A) [amending provisions set out as notes above], the Secretary of Health and Human Services may not implement the Nutrition Labeling and Education Act of 1990 (Public Law 101-535; 104 Stat. 2353) [see Short Title of 1990 Amendments note set out under section 301 of this title], or any amendment made by such Act, earlier than December 15, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances."

HEALTH CLAIMS MADE WITH RESPECT TO DIETARY SUPPLEMENTS

Section 202(b) of Pub. L. 102-571 provided that: "Notwithstanding section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(5)(D)) and subsection (a) [enacting provisions set out as notes above and amending provisions set out as notes above and under section 343-1 of this title], the Secretary of Health and Human Services may, earlier than December 15, 1993, approve claims made with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances that are claims described in clauses (vi) and (x) of section 3(b)(1)(A) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535] (21 U.S.C. 343 note)."

UNITED STATES RECOMMENDED DAILY ALLOWANCES OF VITAMINS OR MINERALS

Section 203 of Pub. L. 102-571 provided that: "Notwithstanding any other provision of Federal law, no regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals may be promulgated before November 8, 1993 (other than regulations establishing the United States recommended daily allowances specified at section 101.9(c)(7)(iv) of title 21, Code of Federal Regulations, as in effect on October 6, 1992, or regulations under section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(1)(A)) that are based on such recommended daily allowances)."

CONSUMER EDUCATION

Section 2(c) of Pub. L. 101-535 provided that: "The Secretary of Health and Human Services shall carry out activities which educate consumers about—

"(1) the availability of nutrition information in the label or labeling of food, and

"(2) the importance of that information in maintaining healthy dietary practices."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 337, 343-1, 345, 347, 350, 371 of this title.

§ 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), or 343(i)(2) of this title that is not identical to the requirement of such section,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a) of this section, under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

(June 25, 1938, ch. 675, § 403A, as added Nov. 8, 1990, Pub. L. 101-535, § 6(a), 104 Stat. 2362; amended Aug. 17, 1991, Pub. L. 102-108, § 2(b), 105 Stat. 549.)

REFERENCES IN TEXT

Section 6(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535], referred to in subsec. (a), is set out below.

AMENDMENTS

1991—Subsec. (a)(5). Pub. L. 102-108 substituted "section 343(r)(5)(B) of this title" for "clause (B) of such section".

EFFECTIVE DATE

Section 10(b) of Pub. L. 101-535, as amended by Pub. L. 102-571, title I, § 107(16), title II, § 202(a)(4), Oct. 29, 1992, 106 Stat. 4499, 4501, provided that:

"(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by section 6 [enacting this section] shall take effect—

"(A) with respect to a requirement of a State or political subdivision described in paragraph (1) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act [subsec. (a)(1) of this section], on the date of the enactment of this Act [Nov. 8, 1990],

"(B) with respect to a requirement of a State or political subdivision described in paragraph (2) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, one year after the date of the enactment of this Act,

"(C) with respect to a requirement of a State or political subdivision described in paragraph (3) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, as prescribed by section 6(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535, set out below],

"(D) with respect to a requirement of a State or political subdivision described in paragraph (4) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(q) of such Act [21 U.S.C. 343(q)] take effect, and

"(E) with respect to a requirement of a State or political subdivision described in paragraph (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(r) of such Act take effect.

"(2) EXCEPTION.—If a State or political subdivision submits a petition under section 403A(b) of the Federal Food, Drug, and Cosmetic Act for a requirement described in section 403A(a) of such Act within 18 months of the date of the enactment of this Act, paragraphs (3) through (5) of such section 403A(a) shall not apply with respect to such State or political subdivision requirement until—

"(A) 24 months after the date of the enactment of this Act, or

"(B) action on the petition,

whichever occurs later.

"(3) REQUIREMENTS PERTAINING TO CERTAIN CLAIMS.—Notwithstanding subparagraphs (D) and (E) of paragraph (1) and except with respect to claims approved in accordance with section 202(b) of the Dietary Supplement Act of 1992 [Pub. L. 102-571, set out as a note under section 343 of this title], the requirements described in paragraphs (4) and (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(4) and (5)) that pertain to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not take effect until the date final regulations take effect to implement subsection (q) or (r), as appropriate, of section 403 of such Act with respect to such dietary supplements."

Section 6(b) of Pub. L. 101-535 provided that:

"(1) For the purpose of implementing section 403A(a)(3) [21 U.S.C. 343-1(a)(3)], the Secretary of Health and Human Services shall enter into a contract with a public or nonprofit private entity to conduct a study of—

"(A) State and local laws which require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(b), (d), (f), (h), (i)(1), (k)], and

"(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

"(2) The contract under paragraph (1) shall provide that the study required by such paragraph shall be completed within 6 months of the date of the enactment of this Act [Nov. 8, 1990].

"(3)(A) Within 9 months of the date of the enactment of this Act, the Secretary shall publish a proposed list of sections which are adequately being implemented by regulations as determined under paragraph (1)(B) and sections which are not adequately being implemented by regulations as so determined. After publication of the lists, the Secretary shall provide 60 days for comments on such lists.

"(B) Within 24 months of the date of the enactment of this Act, the Secretary shall publish a final list of sections which are adequately being implemented by regulations and a list of sections which are not adequately being implemented by regulations. With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to the requirement of such section.

"(C) Within 24 months of the date of the enactment of this Act, the Secretary shall publish proposed revisions to the regulations found to be inadequate under subparagraph (B) and within 30 months of such date shall issue final revisions. Upon the effective date of such final revisions, no State or political subdivision may establish or continue in effect any requirement which is not identical to the requirement of the section which had its regulations revised in accordance with this subparagraph.

"(D)(i) If the Secretary does not issue a final list in accordance with subparagraph (B), the proposed list issued under subparagraph (A) shall be considered the final list and States and political subdivisions shall be preempted with respect to sections found to be adequate in such proposed list in accordance with subparagraph (B).

"(ii) If the Secretary does not issue final revisions of regulations in accordance with subparagraph (C), the proposed revisions issued under such subparagraph shall be considered the final revisions and States and political subdivisions shall be preempted with respect to sections the regulations of which are revised by the proposed revisions.

"(E) Subsection (b) of section 403A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the prohibition prescribed by subparagraphs (B) and (C)."

CONSTRUCTION OF PUB. L. 101-535

Section 6(c) of Pub. L. 101-535 provided that:

"(1) The Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535, see Short Title of 1990 Amendment note set out under section 301 of this title] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act [this section].

"(2) The amendment made by subsection (a) [enacting this section] and the provisions of subsection (b) [set out as a note above] shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

"(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act [this chapter] not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code."

Amendments by Pub. L. 101-535 not to be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

DELAYED APPLICABILITY OF CERTAIN PROVISIONS

Pub. L. 102-408, title III, § 310, Oct. 13, 1992, 106 Stat. 2090, provided that: "Notwithstanding any other

provision of law, section 403A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(1)) shall not apply with respect to any requirement of any State or political subdivision regarding maple syrup until September 1, 1994."

§ 345. Regulations making exemptions

[*See main edition for text*]

(As amended Nov. 8, 1990, Pub. L. 101-535, § 5(a), 104 Stat. 2362.)

AMENDMENT OF SECTION

Pub. L. 101-535, §§ 5(a), 10(a), Nov. 8, 1990, 104 Stat. 2362, 2365, provided that, effective six months after the date of promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with certain exceptions, this section is amended by inserting at the end "This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title."

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101-535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 343 of this title.

§ 346a. Tolerances for pesticide chemicals in or on raw agricultural commodities

[*See main edition for text of (a) to (f)*]

(g) Advisory committees; appointment; composition; compensation; clerical assistance

Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Administrator otherwise deems such referral necessary the Administrator shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Administrator. Members of an advisory committee shall receive compensation and travel expenses in accordance with subsection (b)(5)(D) of section 379e of this title. The members shall not be subject to any other provision of law regarding the appointment and compensation of employees of the United States. The Administrator shall furnish the Committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

[*See main edition for text of (h) to (o)*]

(As amended June 16, 1992, Pub. L. 102-300, § 6(b)(1), 106 Stat. 240; Oct. 29, 1992, Pub. L. 102-571, title I, § 107(7), 106 Stat. 4499.)

AMENDMENTS

1992—Subsecs. (a), (d), (h), (i), (l), (m), (o). Pub. L. 102-300 substituted "Health and Human Services" for "Health, Education, and Welfare" wherever appearing in the original statutory text. See Transfer of Functions note below.

Subsec. (g). Pub. L. 102-571 substituted "379e" for "376".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 342, 346b, 453, 601, 1033 of this title; title 7 section 450i.

§ 347. Intrastate sales of colored oleomargarine

[*See main edition for text of (a) to (c)*]

(d) Exemption from labeling requirements

Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this title (except paragraphs (a) and (f)) if it complies with the requirements of subsection (b) of this section.

[*See main edition for text of (e); credits*]

CODIFICATION

Subsec. (d) of this section is set out in this supplement to correct error appearing in the main edition.

§ 348. Food additives

MORATORIUM ON AUTHORITY OF SECRETARY WITH RESPECT TO SACCHARIN

Pub. L. 95-203, § 3, Nov. 23, 1977, 91 Stat. 1452, as amended by Pub. L. 96-88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 96-273, June 17, 1980, 94 Stat. 536; Pub. L. 97-42, § 2, Aug. 14, 1981, 95 Stat. 946; Pub. L. 98-22, § 2, Apr. 22, 1983, 97 Stat. 173; Pub. L. 99-46, May 24, 1985, 99 Stat. 81; Pub. L. 100-71, title I, § 101, July 11, 1987, 101 Stat. 431; Pub. L. 102-142, title VI, Oct. 28, 1991, 105 Stat. 910, provided that: "During the period ending May 1, 1997, the Secretary—

[*See main edition for text of (1) and (2)*]

solely on the basis of the carcinogenic or other toxic effect of saccharin as determined by any study made available to the Secretary before the date of the enactment of this Act [Nov. 23, 1977] which involved human studies or animal testing, or both."

For definition of "saccharin" as used in this note, see section 2(d) of Pub. L. 95-203.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 379e, 453, 601, 1033 of this title; title 7 section 450i; title 15 section 1262; title 35 section 155.

§ 350. Vitamins and minerals

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 343 of this title.

§ 350a. Infant formulas

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 343, 374 of this title.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 379e(a) of this title, or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title.

(b) Strength, quality, or purity differing from official compendium

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium

If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

[*See main edition for text of* (d) *and* (e)]

(f) Certain class III devices

(1) If it is a class III device—

(A) [*See main edition for text of* (i)]

(ii) [*See main edition for text of* (I)]

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B) [*See main edition for text of* (i)]

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 360j(*l*) of this title into class III, which under such section is required to have in effect an approved application under section 360e of this title, and which has an application which has been suspended or is otherwise not in effect.

[*See main edition for text of* (2); (g) *to* (i)]

(As amended Nov. 28, 1990, Pub. L. 101-629, § 9(b), 104 Stat. 4521; Oct. 29, 1992, Pub. L. 102-571, title I, § 107(8), 106 Stat. 4499.)

CODIFICATION

Pars. (b) and (c) are set out in this supplement to correct error appearing in the main edition.

AMENDMENTS

1992—Par. (a)(4). Pub. L. 102-571 substituted "379e(a)" for "376(a)" in cls. (A) and (B).

1990—Par. (f)(1). Pub. L. 101-629, § 9(b), which directed the amendment of subpars. (A) to (C) of par. (f), was executed by making the amendments in cls. (A) to (C) of subpar. (1) of par. (f) as follows to reflect the probable intent of Congress: in cl. (A)(ii)(II), substituted ", suspended, or withdrawn" for "or withdrawn"; in cl. (B)(ii), substituted "which has an application which has been suspended or is otherwise not in effect" for "which does not have such an application in effect"; and in cl. (C), substituted "which has an application which has been suspended or is otherwise not in effect" for "which does not have such an application in effect".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 333, 334, 356, 357, 360b, 360c, 360j, 371, 379e, 382 of this title.

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

[See main edition for text of (a)]

(b) Package form; contents of label

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

[See main edition for text of (c) to (e)]

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug

If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not those of the United States Pharmacopoeia: *Provided further*, That, in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

[See main edition for text of (h) to (k)]

(l) Antibiotic drugs improperly certified

If it is, or purports to be, or is represented as a drug (except a drug for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 357(c) or (d) of this title.

(m) Color additives; packing and labeling

If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 379e of this title.

(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances

In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in paragrah (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title: *Provided*, That (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of title 15. This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title. Noth-

ing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers.

[*See main edition for text of* (o) *to* (s)]

(t) Devices for which there has been a failure or refusal to give required notification or to furnish required material or information

If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 360h of this title respecting the device, (2) to furnish any material or information required by or under section 360i of this title respecting the device, or (3) to comply with a requirement under section 360*l* of this title.

(As amended June 16, 1992, Pub. L. 102-300, § 3(a)(2), 106 Stat. 239; Oct. 29, 1992, Pub. L. 102-571, title I, § 107(9), 106 Stat. 4499.)

CODIFICATION

Pars. (b), (f), (g), (*l*), and (n) of this section are set out in this supplement to correct error appearing in the main edition.

AMENDMENTS

1992—Par. (m). Pub. L. 102-571 substituted "379e" for "376".

Par. (t)(3). Pub. L. 102-300 added cl. (3).

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 353, 357, 360, 360c, 360j, 371, 602 of this title; title 42 section 1396r-8.

§ 353. Exemptions and consideration for certain drugs, devices, and hiological products

[*See main edition for text of* (a)]

(h) Prescription by pbysician; exemption from labeling and prescription requirements; mishranded drugs; compliance witb narcotic and marihuana laws

[*See main edition for text of* (*1*)]

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (*l*), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

[*See main edition for text of* (*3*) *to* (*5*); (c)]

(d) Distrihution of drug samples

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

[*See main edition for text of* (i)]

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

[*See main edition for text of* (*B*)]

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

[*See main edition for text of* (*i*) *and* (*ii*)]

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples

under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) of this section or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(e) Wholesale distributors; guidelines for licensing; definitions

(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) of this section and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

(B) Each manufacturer of a drug subject to subsection (b) of this section shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) of this section in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B) or has registered with the Secretary in accordance with paragraph (3).

[*See main edition for text of (B)*]

(3) Any person who engages in the wholesale distribution in interstate commerce of drugs that are subject to subsection (b) of this section in a State that does not have a program that meets the guidelines established under paragraph (2)(B) shall register with the Secretary the following:

(A) The person's name and place of business.

(B) The name of each establishment the person owns or operates that is engaged in the wholesale distribution of drugs in a State that does not have a program to license persons engaged in such distribution.

(4) For the purposes of this subsection and subsection (d) of this section—

(A) the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

(B) the term "wholesale distribution" means distribution of drugs subject to subsection (b) of this section to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B) of this section.

(f) Veterinary prescription drugs

(1)(A) A drug intended for use by animals other than man which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 360b of this title to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) shall be exempt from the requirements of section 352 of this title, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filling, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 360b of this title from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.". A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g) Regulation of combination products

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market clearance procedures in accordance with paragraphs (1) and (2) not later than 1 year after November 28, 1990.

(4) As used in this subsection:

(A) The term "biological product" has the meaning given the term in section 262(a) of title 42.

(B) The term "market clearance" includes—

(i) approval of an application under section 355, 357, 360e, or 360j(g) of this title,

(ii) a finding of substantial equivalence under this part, and

(iii) approval of a product or establishment license under subsection (a) or (d) of section 262 of title 42.

(As amended Nov. 28, 1990, Pub. L. 101-629, § 16(a), 104 Stat. 4526; Aug. 17, 1991, Pub. L. 102-108, § 2(d), 105 Stat. 550; June 16, 1992, Pub. L. 102-300, § 6(d), 106 Stat. 240; Aug. 26, 1992, Pub. L. 102-353, §§ 2(a)-(c), 4, 106 Stat. 941, 942.)

AMENDMENT OF SECTION

For termination of amendment by section 2(d) of Pub. L. 102-353, see Termination Date of 1992 Amendment note below.

CODIFICATION

Subsec. (b)(2) of this section is set out in this supplement to correct error appearing in the main edition.

AMENDMENTS

1992—Subsec. (d)(1). Pub. L. 102-353, § 4(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Except as provided in paragraphs (2) and (3), no representative of a drug manufacturer or distributor may distribute any drug sample."

Subsec. (d)(2). Pub. L. 102-353, § 4(2), substituted "authorized distributor of record" for "distributor" wherever appearing.

Subsec. (d)(3). Pub. L. 102-353, § 4(2), substituted "authorized distributor of record" for "distributor" and "authorized distributors of record" for "distributors" wherever appearing.

Subsec. (e)(1). Pub. L. 102-353, § 4(3), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) of this section and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors."

Subsec. (e)(2)(A). Pub. L. 102-353, § 2(a), (d), temporarily inserted "or has registered with the Secretary in accordance with paragraph (3)". See Termination Date of 1992 Amendment note below.

Subsec. (e)(3). Pub. L. 102-353, § 2(b), (d), temporarily added par. (3). Former par. (3) redesignated (4). See Termination Date of 1992 Amendment note below.

Subsec. (e)(4). Pub. L. 102-353, § 4(4), inserted "and subsection (d) of this section" after "For the purposes of this subsection".

Pub. L. 102-353, § 2(b), (d), temporarily redesignated par. (3) as (4). See Termination Date of 1992 Amendment note below.

Subsec. (f)(1)(B). Pub. L. 102-353, § 2(c), which directed the substitution of "an order" for "and order", could not be executed because "and order" did not appear in subpar. (B).

Subsec. (g)(3). Pub. L. 102-300 substituted "clearance" for "approval".

1991—Subsec. (c). Pub. L. 102-108, § 2(d)(3), redesignated subsec. (c), relating to veterinary prescription drugs, as (f). Former subsec. (f) redesignated (g).

Subsec. (c)(2), (3)(B)(v). Pub. L. 102-108, § 2(d)(1), made technical amendment to reference to subsection

(b) of this section involving corresponding provision of original act.

Subsec. (d)(3)(E). Pub. L. 102-108, § 2(d)(2), made technical amendment to reference to subsection (c)(1) of this section involving corresponding provision of original act.

Subsec. (f). Pub. L. 102-108, § 2(d)(4), redesignated subsec. (f), relating to regulation of combination products, as (g).

Pub. L. 102-108, § 2(d)(3), redesignated subsec. (e), relating to veterinary prescription drugs, as (f).

Subsec. (g). Pub. L. 102-108, § 2(d)(4), redesignated subsec. (f), relating to regulation of combination products, as (g).

1990—Pub. L. 101-629, § 16(a)(1), substituted "Exemptions and consideration for certain drugs, devices, and biological products" for "Exemptions in case of drugs and devices" in section catchline.

Subsec. (f). Pub. L. 101-629, § 16(a)(2), added subsec. (f).

TERMINATION DATE OF 1992 AMENDMENT

Section 2(d) of Pub. L. 102-353 provided that: "Effective September 14, 1994, the amendments made by subsections (a) and (b) [amending this section] shall no longer be in effect."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 360, 379g, 381, 825, 829, 885 of this title; title 15 section 1459; title 35 section 156.

§ 355. New drugs

[*See main edition for text of (a) to (i)*]

(j) Abbreviated new drug applications

[*See main edition for text of (1) to (7)*]

(8) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

[*See main edition for text of (k) to (m)*]

(As amended May 13, 1992, Pub. L. 102-282, § 5, 106 Stat. 161.)

AMENDMENTS

1992—Subsec. (j)(8). Pub. L. 102-282 added par. (8).

CONSTRUCTION OF AMENDMENTS BY PUB. L. 102-282

Amendment by Pub. L. 102-282 not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102-282, see section 7 of Pub. L. 102-282, set out as a note under section 335a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 333, 334, 335a, 353, 357, 360, 360b, 360j, 360aa to 360ee, 374, 379g, 379h, 381, 382, 802, 811, 827 of this title; title 16 section 4804; title 26 section 28; title 28 section 2201; title 35 sections 155A, 156, 271; title 42 sections 236, 300cc-12, 300cc-13, 300cc-17, 1395y, 1396r-8.

§ 356. Certification of drugs containing insulin

[*See main edition for text*]

(As amended June 16, 1992, Pub. L. 102-300, § 6(b)(2), 106 Stat. 240.)

AMENDMENTS

1992—Subsec. (a). Pub. L. 102-300, which directed the amendment of subsec. (a) by striking out "of Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. Previously, references to the Secretary of Health and Human Services were substituted for references to the Federal Security Administrator pursuant to the provisions cited in the Change of Name and Transfer of Functions notes set out below.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360 of this title; title 15 section 1459; title 38 section 8126; title 42 section 1396r-8.

§ 357. Certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug

[*See main edition for text*]

(As amended June 16, 1992, Pub. L. 102-300, § 6(b)(2), 106 Stat. 240.)

AMENDMENTS

1992—Subsec. (a). Pub. L. 102-300, which directed the amendment of subsec. (a) by striking out "of Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. Previously, references to the Secretary of Health and Human Services were substituted for references to the Federal Security Administrator pursuant to the provisions cited in the Change of Name and Transfer of Functions notes set out below.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 335a, 352, 353, 360, 360j, 360aa, 360bb, 360cc, 360ee, 374, 379g of this title; title 26 section 28; title 35 section 156; title 42 section 1396r-8.

§ 360. Registration of producers of drugs or devices

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 355, 360c, 360e, 360i, 360j, 379h, 381 of this title.

§ 360b. New animal drugs

[*See main edition for text of (a) to (d)*]

(e) Witbdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals

(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds—

[*See main edition for text of (A)*]

(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) of this section applies to such drug;

[*See main edition for text of (C) to (F)*]

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

[*See main edition for text of (2) and (3); (f) to (p)*]

(As amended Aug. 17, 1991, Pub. L. 102-108, § 2(e), 105 Stat. 550.)

AMENDMENTS

1991—Subsec. (e)(1)(B). Pub. L. 102-108 substituted "(I)" for "(H)".

§ 360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

[*See main edition for text of (i)*]

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

[*See main edition for text of (I) and (II)*]

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

[*See main edition for text of (ii)*]

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

[*See main edition for text of (2) and (3); (b) to (d)*]

(e) Classification changes

(1) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) of this section a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 360d of this title for such device.

(2) By regulation promulgated under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasona-

ble assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(f) Initial classification and reclassification of certain devices

[See main edition for text of (1)]

(2)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petltion which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be used under subsection (b) of this section. A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

[See main edition for text of (ii), (C)]

(3) If a manufacturer reports to the Secretary under section 360(k) of this title that a device is substantially equivalent to another device—

(A) which the Secretary has classifled as a class III device under subsection (b) of this section,

(B) which was introduced or delivered for introductlon into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been promulgated under section 360e(b) of thls title,

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 360(k) of this title a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 360(k) report is being made and which has not been submitted to the Secretary under section 360i of thls title. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

[See main edition for text of (g) and (h)]

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(*l*) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detalled information regarding data concerning adverse health effects and shall be made available to the publlc by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 4(a), 5(a)-(c)(1), (3), 12(a), 18(a), 104 Stat. 4515, 4517, 4518, 4523, 4528; June 16, 1992, Pub. L. 102-300, § 6(e), 106 Stat. 240.)

AMENDMENTS

1992—Subsec. (f)(3). Pub. L. 102-300 redesignated clauses (i) to (iii) as subpars. (A) to (C), respectively, and substituted "the section 360(k) report" for "the 360(k) report" in closing provisions.

1990—Subsec. (a)(1)(A)(ii). Pub. L. 101-629, § 5(a)(1), substituted "or to establish special controls" for "or to establish a performance standard".

Subsec. (a)(1)(B). Pub. L. 101-629, § 5(a)(2), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 360d of this title to provide reasonable assurance of its safety and effectiveness."

Subsec. (a)(1)(C)(i). Pub. L. 101-629, § 5(a)(3), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: "it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and".

Subsec. (e). Pub. L. 101-629, § 5(b), designated existing provisions as par. (1), redesignated cls. (1) and (2) as (A) and (B), respectively, and added par. (2).

Subsec. (f). Pub. L. 101-629, § 5(c)(3), inserted "and reclassification" before "of" in heading.

Subsec. (f)(2)(A). Pub. L. 101-629, § 5(c)(1), substituted "The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer" for "The manufacturer".

Subsec. (f)(2)(B)(i). Pub. L. 101-629, § 18(a), substituted "the Secretary may for good cause shown" for "the Secretary shall".

Subsec. (f)(3). Pub. L. 101-629, § 4(a), added par. (3).

Subsec. (i). Pub. L. 101-629, § 12(a), added subsec. (i).

REGULATIONS

Section 12(b) of Pub. L. 101-629 provided that: "Within 12 months of the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall issue regulations establishing the requirements of the summaries under section 513(i)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360c(i)(3)], as added by the amendment made by subsection (a)."

DAILY WEAR SOFT OR DAILY WEAR' NONHYDROPHILIC PLASTIC CONTACT LENSES

Section 4(b)(3) of Pub. L. 101-629 provided that:

"(A) Notwithstanding section 520(*l*)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(*l*)(5)], the Secretary of Health and Human Services shall not retain any daily wear soft or daily wear nonhydrophilic plastic contact lens in class III under such Act [this chapter] unless the Secretary finds that it meets the criteria set forth in section 513(a)(1)(C) of such Act [21 U.S.C. 360c(a)(1)(C)]. The finding and the grounds for the finding shall be published in the Federal Register. For any such lens, the Secretary shall make the determination respecting reclassification required in section 520(*l*)(5)(B) of such Act within 24 months of the date of the enactment of this paragraph [Nov. 28, 1990].

"(B) The Secretary of Health and Human Services may by notice published in the Federal Register extend the two-year period prescribed by subparagraph (A) for a lens for an additional period not to exceed one year.

"(C)(i) Before classifying a lens in class II pursuant to subparagraph (A), the Secretary of Health and Human Services shall pursuant to section 513(a)(1)(B) of such Act assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

"(ii) Prior to classifying a lens in class I pursuant to subparagraph (A), the Secretary shall assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

"(D) Notwithstanding section 520(*l*)(5) of such Act, if the Secretary of Health and Human Services has not made the finding and published the finding required by subparagraph (A) within 36 months of the date of the enactment of this subparagraph [Nov. 28, 1990], the Secretary shall issue an order placing the lens in class II.

"(E) Any person adversely affected by a final regulation under this paragraph revising the classification of a lens may challenge the revision of the classification of such lens only by filing a petition under section 513(e) for a classification change."

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 360, 360d, 360e, 360g, 360j of this title.

§ 360d. Performance standards

(a) Reasonable assurance of safe and effective performance; periodic evaluation

(1) The special controls required by section 360c(a)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under this section if the device has been reclassified as a class II device under a regulation under section 360c(e) of this title but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

[*See main edition for text of* (2) *to* (4)]

(b) Establisbment of a standard

(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is ap-

propriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,

(iii) Invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 360c(e) of this title based on new information relevant to the classification, and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of not less than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 360c of this title, either deny the request or give notice of an intent to initiate such change under section 360c(e) of this title.

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Sec-

retary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 6(a), (b)(1), 18(b), 104 Stat. 4519, 4528; June 16, 1992, Pub. L. 102-300, § 6(g), 106 Stat. 241.)

AMENDMENTS

1992—Subsec. (b)(4)(B), (5)(A)(ii). Pub. L. 102-300 made technical corrections to directory language of Pub. L. 101-629, § 18(b)(1), (2). See 1990 Amendment note below.

1990—Subsec. (a)(1). Pub. L. 101-629, § 6(a)(1), substituted "The special controls required by section 360c(a)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device." for "The Secretary may by regulation, promulgated in accordance with this section, establish a performance standard for a class II device."

Subsec. (b). Pub. L. 101-629, § 6(a)(2), (3), redesignated subsec. (g) as (b) and struck out former subsec. (b) which read as follows:

"(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification.

"(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title."

Subsec. (b)(1), (2). Pub. L. 101-629, § 6(a)(4), amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

"(1)(A) After publication pursuant to subsection (c) of this section of a notico respecting a performance standard for a device, the Secretary shall either—

"(i) publish, in the Federal Register in a notice of proposed rulemaking, a proposed performance standard for the device (I) developed by an offeror under such notice and accepted by the Secretary, (II) developed under subsection (c)(4) of this section, (III) accepted by the Secretary under subsection (d) of this section, or (IV) developed by him under subsection (f) of this section, or

"(ii) issue a notice in the Federal Register that the proceeding is terminated together with the reasons for such termination.

"(B) If the Secretary issues under subparagraph (A)(ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

"(2) A notice of proposed rulemaking for the establishment of a performance standard for a device published under paragraph (1)(A)(i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device."

Subsec. (b)(3)(A)(i). Pub. L. 101-629, § 6(b)(1)(A), substituted "paragraph (1)" for "paragraph (2)".

Subsec. (b)(4)(A). Pub. L. 101-629, § 6(b)(1)(B), substituted "paragraphs (1), (2), and (3)(B)" for "paragraphs (2) and (3)(B)".

Subsec. (b)(4)(B). Pub. L. 101-629, § 18(b)(1), as amended by Pub. L. 102-300, § 6(g)(1), (2), struck out ", after affording all interested persons an opportunity for an informal hearing," after "if he determines".

Subsec. (b)(5)(A)(ii). Pub. L. 101-629, § 18(b)(2), as amended by Pub. L. 102-300, § 6(g)(1), (3), substituted "which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation," for "unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,".

Subsecs. (c) to (f). Pub. L. 101-629, § 6(a)(2), struck out subsec. (c) relating to invitations for standards, subsec. (d) relating to acceptance of certain existing standards, subsec. (e) relating to acceptance of offers to develop standards, and subsec. (f) relating to development of standards by the Secretary after publication of notice inviting submissions or offers of standards.

Subsec. (g). Pub. L. 101-629, § 6(a)(3), redesignated subsec. (g) as (b).

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

§ 360e. Premarket approval

[*See main edition for text of (a) and (b)*]

(c) Application for premarket approval

[*See main edition for text of (1)*]

(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may on the Secretary's own initiative refer such application,[1] or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 360c of this title,

[1] So in original. The words "refer such application" probably should not appear.

refer such application to the appropriate panel under section 360c of this title for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

[*See main edition for text of (d)*]

(e) Withdrawal and temporary suspension of approval of application

[*See main edition for text of (1) and (2)*]

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

[*See main edition for text of (f) to (h)*]

(i) Revision

(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before December 1, 1995, the Secretary shall publish a regulation in the Federal Register for each device—

(A) which the Secretary has classified as a class III device, and

(B) for which no final regulation has been promulgated under subsection (b) of this section,

revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title. Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this paragraph and provide reasonable opportunity for the submission of comments on any such regulation. No regulation requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of its publication in the Federal Register as a proposed regulation.

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the regulation requiring a device to remain in class III, establish a schedule for the promulgation of a subsection (b) of this section regulation for each device which is subject to the regulation requiring the device to remain in class III.

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 4(b)(1), 9(a), 18(c), 104 Stat. 4515, 4521, 4528.)

AMENDMENTS

1990—Subsec. (c)(2). Pub. L. 101-629, § 18(c), substituted "the Secretary—" for "the Secretary shall" and added subpars. (A) and (B).

Subsec. (e). Pub. L. 101-629, § 9(a)(2), inserted "and temporary suspension" after "Withdrawal" in heading.

Subsec. (e)(3). Pub. L. 101-629, § 9(a)(1), added par. (3).

Subsec. (i). Pub. L. 101-629, § 4(b)(1), added subsec. (i).

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 353, 360, 360c, 360g, 360j, 381 of this title; title 35 section 156.

§ 360f. Banned devices

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information, that—

[*See main edition for text of (1) and (2)*]

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

[*See main edition for text of (b)*]

(As amended Nov. 28, 1990, Pub. L. 101-629, § 18(d), 104 Stat. 4529.)

AMENDMENTS

1990—Subsec. (a). Pub. L. 101-629 struck out "and after consultation with the appropriate panel or panels under section 360c of this title" after "data and information" in introductory provisions and struck out at end "The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection."

§ 360g. Judicial review

(a) Petition; record

Not later than thirty days after—

[*See main edition for text of (1) to (5)*]

(6) the issuance of an order under section 360j(f)(2) of this title,

[*See main edition for text of* (7)]

(8) an order pursuant to section 360c(i) of this title,

(9) a regulation under section 360e(i)(2) or 360j(*l*)(5)(B) of this title, or

(10) an order under section 360j(h)(4)(B) of this title,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial revlew of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28. For purposes of this section, the term "record" means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

[*See main edition for text of* (b) *to* (f)]

(As amended Nov. 28, 1990, Pub. L. 101-629, § 13, 104 Stat. 4524; June 16, 1992, Pub. L. 102-300, § 6(f), 106 Stat. 240.)

AMENDMENTS

1992—Subsec. (a)(10). Pub. L. 102-300 substituted "360j(h)(4)(B)" for "360j(c)(4)(B)".

1990—Subsec. (a)(8) to (10). Pub. L. 101-629 added pars. (8) to (10).

§ 360h. Notification and other remedies

[*See main edition for text of* (a)]

(b) Repair, replacement, or refund

(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

[*See main edition for text of* (i)]

(ii) there are reasonable grounds to believe that the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its desigu or manufacture,

[*See main edition for text of* (iii) *and* (iv)]

the Secretary may order the manufacturer, importer, or any distributor of such devlce, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responslbility.

[*See main edition for text of* (B), (2) *and* (3); (c) *and* (d)]

(e) Recall authority

(1) If the Secretary finds that there is a reasonable probabillty that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retallers of the device)—

(A) to immediately cease distribution of such device, and

(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) An amended order under subparagraph (A)—

(i) shall—

(I) not include recall of a device from individuals, and

(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facillties presents a greater health risk than the health risk of not recalling the device from use, and

(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health

professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 375(b) of this title.

(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c) of this section.

(As amended Nov. 28, 1990, Pub. L. 101-629, § 8, 104 Stat. 4520; June 16, 1992, Pub. L. 102-300, § 4, 106 Stat. 239.)

AMENDMENTS

1992—Subsec. (b)(1)(A)(ii). Pub. L. 102-300 substituted "or" for "and" after "properly designed" and "time of its design".

1990—Subsec. (e). Pub. L. 101-629 added subsec. (e).

§ 360i. Records and reports on devices

(a) General rule

Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

(1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

(A) may have caused or contributed to a death or serious injury, or

(B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;

(2) shall define the term "serious injury" to mean an injury that—

(A) is life threatening,

(B) results in permanent impairment of a body function or permanent damage to a body structure, or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

(4) shall not impose requirements unduly burdensome to a device manufacturer, importer, or distributor taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

(5) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(6) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

(7) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this chapter;

(8) may not require a manufacturer, importer, or distributor of a class I device to—

(A) maintain for such a device records respecting information not in the possession of the manufacturer, importer, or distributor, or

(B) to submit for such a device to the Secretary any report or information—

(i) not in the possession of the manufacturer, importer, or distributor, or

(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded; and

(9) shall require distributors who submit such reports to submit copies of the reports to the manufacturer of the device for which the report was made.

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (4) [1] of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(b) User reports

(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

(B) Whenever a device user facility receives or otherwise becomes aware of—

(i) information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility, or

[1] See References in Text note below.

(ii) other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported,

the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

(C) Each device user facility shall submit to the Secretary on a semi-annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 and July 1 of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include—

(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

(ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

(iii) the name and the address of the manufacturer of such device, and

(iv) a brief description of the event reported to the manufacturer.

The Secretary may by regulation alter the frequency and timing of reports required by this subparagraph.

(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

(2) The Secretary may not disclose the identity of a device user facility which makes a report under paragraph (1) except in connection with—

(A) an action brought to enforce section 331(q) of this title,

(B) a communication to a manufacturer of a device which is the subject of a report under paragraph (1), or

(C) a disclosure required under subsection (a) of this section.

This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (1) or any information in such a report to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

(3) No report made under paragraph (1) by—

(A) a device user facility,

(B) an individual who is employed by or otherwise formally affiliated with such a facility, or

(C) a physician who is not required to make such a report,

shall be admissible into evidence or otherwise used in any civil action involving private parties uniess the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a) of this section.

(5) For purposes of this subsection:

(A) The term "device user facility" means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. The Secretary may by regulation include an outpatient diagnostic facility which is not a physician's office in such term.

(B) The terms "serious illness" and "serious injury" mean illness or injury, respectively, that—

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(c) Persons exempt

Subsection (a) of this section shall not apply to—

(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 360j(g) of this title); and

(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) of this section upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

(d) Certification

Each manufacturer, importer, and distributor required to make reports under subsection (a) of this section shall submit to the Secretary annually a statement certifying that—

(1) the manufacturer, importer, or distributor did file a certain number of such reports, or

(2) the manufacturer, importer, or distributor did not file any report under subsection (a) of this section.

(e) Device tracking

Every person who registers under section 360 of this title and is engaged in the manufacture of—

(1) a device the fallure of which would be reasonably likely to have serious adverse health consequences and which is (A) a permanently implantable device, or (B) a life sustaining or life supporting device used outside a device user facility, or

(2) any other device which the Secretary may designate,

shall adopt a method of device tracking.

(f) Report of removals and corrections

(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer, importer, or distributor of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer, importer, or distributor if the removal or correction was undertaken—

(A) to reduce a risk to health posed by the device, or

(B) to remedy a violation of this chapter caused by the device which may present a risk to health.

A manufacturer, importer, or distributor of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a) of this section.

(3) For purposes of paragraphs (1) and (2), the terms "correction" and "removal" do not include routine servicing.

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 2(a), 3(a)(1), (b)(1), 7, 104 Stat. 4511, 4513, 4514, 4520; June 16, 1992, Pub. L. 102-300, § 5(a), 106 Stat. 239.)

REFERENCES IN TEXT

Paragraph (4) of this subsection, referred to in last sentence of subsec. (a), was redesignated par. (7) by Pub. L. 102-300, § 5(a)(1), June 16, 1992, 106 Stat. 239.

AMENDMENTS

1992—Subsec. (a). Pub. L. 102-300, § 5(a)(1), added pars. (1) to (3) and redesignated former pars. (1) to (6) as (4) to (9), respectively.

Subsec. (b)(1)(A). Pub. L. 102-300, § 5(a)(2)(A), substituted "a device has or may have" for "there is a probability that a device has".

Subsec. (b)(1)(B). Pub. L. 102-300, § 5(a)(2)(A), (B), substituted "a device has or may have" for "there is a probability that a device has", designated existing provisions as cl. (i), and added cl. (ii).

Subsec. (b)(5)(B)(iii). Pub. L. 102-300, § 5(a)(2)(C), struck out "immediate" before "medical".

1990—Subsec. (a)(6). Pub. L. 101-629, § 3(a)(1), added par. (6).

Subsecs. (b), (c). Pub. L. 101-629, § 2(a), added subsec. (b) and redesignated former subsec. (b) as (c).

Subsecs. (d), (e). Pub. L. 101-629, § 3(b)(1), added subsecs. (d) and (e).

Subsec. (f). Pub. L. 101-629, § 7, added subsec. (f).

EFFECTIVE DATE OF 1992 AMENDMENT

Section 2(b) of Pub. L. 102-300 provided that: "The amendments made by subsection (a) [amending sections 3(b)(3) and 3(c) of Pub. L. 101-629, set out as notes below] shall take effect as of May 27, 1992 and any rule to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360l(e)] proposed under section 3(c)(2) of the Safe Medical Devices Act of 1990 [Pub. L. 101-629, set out as a note below] shall revert to its proposed status as of such date."

Section 5(b) of Pub. L. 102-300 provided that: "The amendments made by subsection (a) [amending this section] shall take effect—

"(1) 1 year after the date of the enactment of this Act [June 16, 1992]; or

"(2) on the effective date of regulations of the Secretary to implement such amendments,

whichever occurs first."

EFFECTIVE DATE OF 1990 AMENDMENT

Section 2(c) of Pub. L. 101-629 provided that: "Section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)], as added by the amendment made by subsection (a), shall take effect—

"(1) upon the effective date of regulations promulgated under subsection (b) [set out below], or

"(2) upon the expiration of 12 months from the date of the enactment of this Act [Nov. 28, 1990],

whichever occurs first."

Section 3(a)(2) of Pub. L. 101-629 provided that: "Section 519(a)(6) [21 U.S.C. 360i(a)(6)], as added by the amendment made by paragraph (1), shall take effect upon the effective date of final regulations under subsection (c) [set out below]."

Section 3(b)(3) of Pub. L. 101-629, as amended by Pub. L. 102-300, § 2(a)(1), June 16, 1992, 106 Stat. 238, provided that: "Section 519(e) [21 U.S.C. 360l(e)], as added by the amendment made by paragraph (1), shall take effect upon the expiration of 9 months after the issuance of final regulations under subsection (c) [set out below]."

[For effective date of amendment by Pub. L. 102-300, see section 2(b) of Pub. L. 102-300, set out above as an Effective Date of 1992 Amendment note.]

REGULATIONS

Section 2(b) of Pub. L. 101-629 provided that: "The Secretary of Health and Human Services shall promulgate regulations to implement section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)], as added by the amendment made by subsection (a) (including a definition of the summary required by paragraph (1)(C) of such section) not later than 12 months after the date of enactment of this Act [Nov. 28, 1990]. In promulgating the regulations, the Secretary shall minimize the administrative burdens on device user facilities consistent with the need to assure adequate information."

Section 3(c) of Pub. L. 101-629, as amended by Pub. L. 102-300, § 2(a)(2), (3), June 16, 1992, 106 Stat. 238, provided that:

"(1)(A) Not later than 9 months after the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall issue proposed regulations—

"(i) to require distributors of devices to establish and maintain records and to make reports (including reports required by part 803 of title 21 of the Code of Federal Regulations) under section 519(a)(6) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360l(a)(6)], and

"(ii) to implement section 519(e) of such Act.

The Secretary may exempt from regulations described in clause (i) classes of distributors of class I and class II devices from whom reports are not necessary for the protection of the public health.

"(B) Regulations under subparagraph (A) shall—

"(i) require appropriate methods for maintenance of records to ensure that patients who receive devices can be provided the notification required by such Act [this chapter],

"(ii) require that manufacturers adopt effective methods of tracking devices,

"(iii) take into account the position of distributors in the device distribution process, and

"(iv) include such other requirements as the Secretary deems necessary for the adoption of an effective user tracking program under section 519(e) of such Act.

"(2) Not later than 18 months after the date of the enactment of this Act, the Secretary shall issue final

regulations to implement sections [sic] 519(a)(6) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations upon the expiration of such 18 months, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of sections [sic] 519(a)(6) of such Act is essential to protect the health of patients who use such devices. Consequently, in such event, the proposed regulations issued under paragraph (1) shall become final regulations as of the expiration of such 18 months. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations.

"(3) Not later than November 28, 1992, the Secretary shall issue final regulations to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations by November 28, 1992, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of section 519(e) of such Act is essential to protect the health of patients who use devices. In such event, the proposed regulations issued under paragraph (1) shall become the issued final regulations on November 29, 1992. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations."

[For effective date of amendment by Pub. L. 102-300, see section 2(b) of Pub. L. 102-300, set out above as an Effective Date of 1992 Amendment note.]

INFORMATION CONCERNING REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Section 2(d) of Pub. L. 101-629 provided that: "During the 18-month period beginning on the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall inform device user facilities (as defined in section 519(b)(5)(A) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)(5)(A)]) and manufacturers and distributors of devices respecting the requirements of section 519(b) of such Act. Additionally, the Secretary, to the extent practicable, shall provide persons subject to the requirements of such section assistance in the form of publications regarding such requirements."

STUDY OF REPORTING REQUIREMENTS; COMPLIANCE BY DEVICE USER FACILITIES; ACTIONS BY MANUFACTURERS; COST EFFECTIVENESS; RECOMMENDATIONS

Section 2(e) of Pub. L. 101-629 provided that: "Not more than 36 months after the date of the enactment of this Act [Nov. 28, 1990], the Comptroller General of the United States shall conduct a study of—

"(1) the compliance by device user facilities (as defined in section 519(b)(5)(A) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)(5)(A)]) with the requirements of section 519(b) of such Act,

"(2) the actions taken by the manufacturers of devices in response to reports made to them under such section,

"(3) the cost effectiveness of such requirements and their implementation, and

"(4) any recommendations for improvements to such requirements.

The Comptroller General shall complete the study and submit a report on the study not later than 45 months from the date of the enactment of this Act. The report shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate and to the Secretary of Health and Human Services."

REPORT TO CONGRESS ON REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Section 2(f) of Pub. L. 101-629 provided that: "Not later than 36 months after the date of enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that contains an evaluation of the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)]. In preparing the report, the Secretary shall consult with individuals and organizations with an interest in health care and consumer issues. At a minimum, the report shall contain—

"(1) an evaluation of the safety benefits of the requirements,

"(2) an evaluation of the burdens placed on the Food and Drug Administration and on device user facilities by the requirements,

"(3) an evaluation of the cost-effectiveness of the requirements, and

"(4) recommendations for legislative reform."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 352, 360c, 360e, 360g, 360j, 374 of this title.

§ 360j. General provisions respecting control of devices intended for human use

[*See main edition for text of (a) and (b)*]

(c) Trade secrets

Any information reported to or otherwise obtained by the Secretary or his representative under section 360c, 360d, 360e, 360f, 360h, 360i, or 374 of this title or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 360d of this title for a device reclassified from class III to class II, except (1) in accordance with subsection (h) of this section, and (2) that such information may be disclosed to other officers or employees concerned with carrying out this chapter or when relevant in any proceeding under this chapter (other than section 360c or 360d of this title).

[*See main edition for text of (d) and (e)*]

(f) Good manufacturing practice requirements

(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this chapter.

[*See main edition for text of (B)*]

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

[*See main edition for text of (2) and (3)*]

(g) Exemption for devices for investigational use

[*See main edition for text of (1)*]

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i, or 379e of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

[*See main edition for text of (B) and (C), (3) to (5)*]

(h) Release of information respecting safety and effectiveness

[*See main edition for text of (1) and (2)*]

(3) Except as provided in paragraph (4), any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this chapter by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 360e(c) of this title, including clinical and preclinical tests or studies, but excluding descriptions of methods of manufacture and product composition, that demonstrates the safety and effectiveness of a device shall be available 1 year after the original application for the fourth device of a kind has been approved by the Secretary, for use by the Secretary in approving devices, or determining whether a product development protocol has been completed, under section 360e of this title, establishing a performance standard under section 360d of this title, and reclassifying devices under subsections (e) and (f) of section 360c of this title, and subsection (*l*)(2) of this section. The Secretary shall deem devices that incorporate the same technologies, have the same principles of operation, and are intended for the same use or uses to be within a kind of device.

(B) The Secretary, contemporaneously with the approval of the fourth device of a kind, shall publish an order in the Federal Register identifying the four devices of a kind that have been approved under section 360e of this title and the date on which the data contained in premarket approval applications for the devices will be available to the Secretary for use, as described in subparagraph (A).

(C) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the regulatory action described in subparagraph (A).

(D)(i) This paragraph shall become effective—

(I) on November 15, 1990, for devices for which four devices of a kind were approved on or before December 31, 1987, and

(II) on November 15, 1991, for devices not described in subclause (I).

(ii) For each device described in clause (i)(I), the Secretary shall publish a notice in the Federal Register setting forth the date, which shall be not earlier than 1 year after the date of the notice, that data identified in subparagraph (A) shall be available for the use of the Secretary.

(E)(i) Except as provided in clause (ii), the approval date of a device, for purposes of this paragraph, shall be the date of the letter of the Secretary to the applicant approving a device under section 360e of this title and permitting the applicant to commercially distribute the device.

(ii) For each device described in subparagraph (D)(i)(II) for which the original application for a fourth device of a kind is approved by the Secretary before November 1, 1991, the approval date of the fourth device of a kind shall be deemed to be November 15, 1991.

(F) Any challenge to an order under subparagraph (B) shall be made not later than 30 days after the date of the Federal Register notice referred to in such subparagraph.

(i) Proceedings of advisory panels and committees

Each panel under section 360c of this title and each advisory committee established under section 360d(b)(5)(B) or 360e(g) of this title or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

(j) Traceability

Except as provided in section 360i(e) of this title, no regulation under this chapter may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

[*See main edition for text of (k)*]

(*l*) Transitional provisions for devices considered as new drugs or antibiotic drugs

[*See main edition for text of (1)*]

(2) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one

hundred and eighty days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appropriate panel under section 360c of this title, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 360c(a)(1)(A) of this title or 360c(a)(1)(B) of this title, of the device in class I or class II.

[*See main edition for text of (3) and (4)*]

(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title. Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

(m) Humanitarian device exemption

(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 360d and 360e of this title for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

(3) No person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) Devices granted an exemption under paragraph (2) may only be used—

(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to supervise clinical testing of devices in the facilities, and

(B) if, before the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A).

(5) An exemption under paragraph (2) shall be for a term of 18 months and may only be initially granted in the 5-year period beginning on the date regulations under paragraph (6) take effect. The Secretary may extend such an exemption for a period of 18 months if the Secretary is able to make the findings set forth in paragraph (2) and if the applicant supplies information demonstrating compliance with paragraph (3). An exemption may be extended more than once and may be extended after the expiration of such 5-year period.

(6) Within one year of November 28, 1990, the Secretary shall issue regulations to implement this subsection.

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 3(b)(2), 4(b)(2), 5(c)(2), 6(b)(2), 11, 14(a), 18(e), (f), 104 Stat. 4514, 4516, 4518, 4519, 4522, 4524, 4529; Oct. 29, 1992, Pub. L. 102-571, title I, § 107(10), 106 Stat. 4499.)

AMENDMENTS

1992—Subsec. (g)(2)(A). Pub. L. 102-571 substituted "379e" for "376".

1990—Subsec. (c). Pub. L. 101-629, § 11(1), substituted "from class III to class II or class I" for "under section 360c of this title from class III to class II" and inserted "(1) in accordance with subsection (h) of this section, and (2)" after "except".

Subsec. (f)(1)(A). Pub. L. 101-629, § 18(e), inserted "pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device)," after "manufacture,".

Subsec. (h)(3). Pub. L. 101-629, § 11(2)(A), substituted "Except as provided in paragraph (4), any" for "Any".

Subsec. (h)(4). Pub. L. 101-629, § 11(2)(B), added par. (4).

Subsec. (i). Pub. L. 101-629, § 6(b)(2), substituted "section 360d(b)(5)(B)" for "section 360d(g)(5)(B)".

Subsec. (j). Pub. L. 101-629, § 3(b)(2), substituted "Except as provided in section 360i(e) of this title, no" for "No".

Subsec. (*l*)(2). Pub. L. 101-629, § 18(f), struck out "and after affording the petitioner an opportunity for an informal hearing" after "under this paragraph".

Pub. L. 101-629, § 5(c)(2), substituted "The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer" for "The manufacturer".

Subsec. (*l*)(5). Pub. L. 101-629, § 4(b)(2), added par. (5).

Subsec. (m). Pub. L. 101-629, § 14(a), added subsec. (m).

EFFECTIVE DATE OF 1990 AMENDMENT

Section 14(b) of Pub. L. 101-629 provided that: "Subsection (m) of section 520 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(m)], as added by the amendment made by subsection (a), shall take effect on the effective date of the regulations issued by the Secretary under paragraph (6) of such subsection."

REPORT ON HUMANITARIAN DEVICE EXEMPTIONS

Section 14(c) of Pub. L. 101-629 provided that: "Within 4 years after the issuance of regulations under section 520(m)(6) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(m)(6)], as added by the amendment made by subsection (a), the Secretary of Health and Human Services shall report to the Congress (1) on the types of devices exempted under such section, (2) an evaluation of the effects of such section, and (3) a recommendation on extension of the section."

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 351, 352, 353, 360c, 360d, 360e, 360g, 360l, 374, 381, 383 of this title.

§ 360*l*. Postmarket surveillance

(a) In general

(1) Required surveillance

The Secretary shall require a manufacturer to conduct postmarket surveillance for any device of the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, that—

(A) is a permanent implant the failure of which may cause serious, adverse health consequences or death,

(B) is intended for a use in supporting or sustaining human life, or

(C) potentially presents a serious risk to human health.

(2) Discretionary surveillance

The Secretary may require a manufacturer to conduct postmarket surveillance for a device of the manufacturer if the Secretary determines that postmarket surveillance of the device is necessary to protect the public health or to provide safety or effectiveness data for the device.

(b) Surveillance approval

Each manufacturer required to conduct a surveillance of a device under subsection (a)(1) of this section shall, within 30 days of the first introduction or delivery for introduction of such device into interstate commerce, submit, for the approval of the Secretary, a protocol for the required surveillance. Each manufacturer required to conduct a surveillance of a device under subsection (a)(2) of this section shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.

(June 25, 1938, ch. 675, § 522, as added Nov. 28, 1990, Pub. L. 101-629, § 10, 104 Stat. 4521; amended June 16, 1992, Pub. L. 102-300, § 3(b), 106 Stat. 239.)

AMENDMENTS

1992—Subsec. (b). Pub. L. 102-300 substituted "(a)(1)" for "(a)", inserted comma after "commerce", and inserted after first sentence "Each manufacturer required to conduct a surveillance of a device under subsection (a)(2) of this section shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352 of this title.

PART B—DRUGS FOR RARE DISEASES OR CONDITIONS

§ 360ee. Grants and contracts for development of drugs for rare diseases and conditions

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 343 of this title; title 42 section 236.

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

CODIFICATION

This part was classified to subpart 3 (§ 263b et seq.) of part F of subchapter II of chapter 6A of Title 42, The Public Health and Welfare, prior to its renumbering by Pub. L. 101-629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530.

PART REFERRED TO IN OTHER SECTIONS

This part is referred to in title 15 section 2080.

§ 360gg. Repealed. Pub. L. 101–629, § 19(a)(3), Nov. 28, 1990, 104 Stat. 4530

Section, act June 25, 1938, ch. 675, § 530, formerly act July 1, 1944, ch. 373, title III, § 354, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1173; renumbered § 530 of act June 25, 1938, and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (4), 104 Stat. 4529, 4530, set forth Congressional declaration of purpose.

Section was classified to section 263b of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

§ 360hh. Definitions

As used in this part—

(1) the term "electronic product radiation" means—

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

(2) the term "electronic product" means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation;

(3) the term "manufacturer" means any person engaged in the business of manufacturing, assembling, or importing of electronic products;

(4) the term "commerce" means (A) commerce between any place in any State and any place outside thereof; and (B) commerce wholly within the District of Columbia; and

(5) the term "State" includes the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, and American Samoa.

(June 25, 1938, ch. 675, § 531, formerly act July 1, 1944, ch. 373, title III, § 531, formerly § 355, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1174; amended Oct. 12, 1976, Pub. L. 94–484, title IX, § 905(b)(1), 90 Stat. 2325; renumbered § 531 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263c of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1990—Pub. L. 101–629, § 19(a)(3), (4), renumbered section 263c of Title 42, The Public Health and Welfare, as this section.

Pub. L. 101–629, § 19(a)(1)(B), substituted "this part" for "this subpart" in introductory provisions.

1970—Par. (5). Pub. L. 94–484 defined "State" to include Northern Mariana Islands.

SHORT TITLE

For short title of Pub. L. 90–602, which enacted provisions now comprising this part (§§ 360gg to 360ss), as the "Radiation Control for Health and Safety Act of 1968", see section 1 of Pub. L. 90–602, set out as a Short Title of 1968 Amendments note under section 301 of this title.

TRANSFER OF SUBPART; CONSTRUCTION

Section 19(c) of Pub. L. 101–629 provided that: "The transfer of subpart 3 of part F of title III of the Public Health Service Act [42 U.S.C. 263b et seq.] to the Federal Food, Drug, and Cosmetic Act [this chapter] does not change the application of the requirements of such subpart and such Act to electronic products which were in effect on the date of the enactment of this Act [Nov. 28, 1990]."

DEFINITION OF "SECRETARY" AND "DEPARTMENT"

Section 3 of Pub. L. 90–602, as amended Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, provided that: "As used in the amendments made by section 2 of this Act [enacting provisions now comprising sections 360gg to 360ss of this title], except when otherwise specified, the term 'Secretary' means the Secretary of Health and Human Services, and the term 'Department' means the Department of Health and Human Services."

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Section 4 of Pub. L. 90–602 provided that: "The amendments made by section 2 of this Act [enacting provisions now comprising sections 360gg to 360ss of this title] shall not be construed as superseding or limiting the functions, under any other provision of law, of any officer or agency of the United States."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360kk of this title; title 15 section 2080.

§ 360ii. Program of control

(a) Establishment

The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—

(1) pursuant to section 360kk of this title, develop and administer performance standards for electronic products;

(2) plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation;

(3) maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry and labor associations, and other organizations on present and future potential electronic product radiation;

(4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation; and

(6) consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) techniques, equipment, and programs for test-

ing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 360kk of this title to control such radiation emissions.

(b) Powers of Secretary

In carrying out the purposes of subsection (a) of this section, the Secretary is authorized to—

(1)(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation; and (B) make such recommendations relating to such hazards and control as he considers appropriate;

(2) make grants to public and private agencies, organizations, and institutions, and to individuals for the purposes stated in paragraphs (2), (4), and (5) of subsection (a) of this section;

(3) contract with public or private agencies, institutions, and organizations, and with individuals, without regard to section 3324 of title 31 and section 5 of title 41; and

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products.

(c) Record keeping

(1) Each recipient of assistance under this part pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project or undertaking in connection with which such assistance is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts entered into under this part under other than competitive bidding procedures.

(June 25, 1938, ch. 675, § 532, formerly act July 1, 1944, ch. 373, title III, § 532, formerly § 356, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1174; renumbered § 532 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(A), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263d of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263d of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(1), (6). Pub. L. 101-629, § 19(a)(2)(A)(i), substituted "section 360kk" for "section 263f".

Subsec. (b)(3). Pub. L. 101-629, § 19(a)(2)(A)(ii), substituted reference to section 3324 of title 31 for reference to section 3648 of the Revised Statutes (31 U.S.C. 529).

Subsec. (c)(1), (2). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

TRANSFER OF FUNCTIONS

Atomic Energy Commission abolished and functions transferred by sections 5814 and 5841 of Title 42, The Public Health and Welfare. See also Transfer of Functions notes set out under those sections.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law or any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360jj. Studies by Secretary

(a) Report to Congress

The Secretary shall conduct the following studies, and shall make a report or reports of the results of such studies to the Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate:

(1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to—

(A) control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.];

(B) any gaps and inconsistencies in present controls;

(C) the need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading such products to meet the standards for new products or separate standards for used products;

(D) measures to assure consistent and effective control of the aforementioned health hazards;

(E) measures to strengthen radiological health programs of State governments; and

(F) the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation;

(2) A study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes; and

(3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation which may be emitted from electronic products manufactured or imported prior to the effective date of any applicable standard established pursuant to this part.

(b) Participation of other Federal agencies

In carrying out these studies, the Secretary shall invite the participation of other Federal departments and agencies having related re-

sponsibilities and interests, State governments—particularly those of States which regulate radioactive materials under section 274 of the Atomic Energy Act of 1954, as amended [42 U.S.C. 2021], and interested professional, labor, and industrial organizations. Upon request from congressional committees interested in these studies, the Secretary shall keep these committees currently informed as to the progress of the studies and shall permit the committees to send observers to meetings of the study groups.

(c) Organization of studies and participation

The Secretary or his designee shall organize the studies and the participation of the invited participants as he deems best. Any dissent from the findings and recommendations of the Secretary shall be included in the report if so requested by the dissenter.

(June 25, 1938, ch. 675, § 533, formerly act July 1, 1944, ch. 373, title III, § 533, formerly § 357, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1176; renumbered § 533 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530.)

REFERENCES IN TEXT

The Atomic Energy Act of 1954, referred to in subsec. (a)(1)(A), is act Aug. 30, 1954, ch. 1073, § 1, 68 Stat. 921, as amended, which is classified generally to chapter 23 (§ 2011 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 2011 of Title 42 and Tables.

CODIFICATION

Section was classified to section 263e of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263e of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(3). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360kk. Performance standards for electronic products

(a) Promulgation of regulations

(1) The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products. Such standards may be prescribed from time to time whenever such determinations are made, but the first of such standards shall be prescribed prior to January 1, 1970. In the development of such standards, the Secretary shall consult with Federal and State departments and agencies having related responsibilities or interests and with appropriate professional organizations and interested persons, including representatives of industries and labor organizations which would be affected by such standards, and shall give consideration to—

(A) the latest available scientific and medical data in the field of electronic product radiation;

(B) the standards currently recommended by (i) other Federal agencies having responsibilities relating to the control and measurement of electronic product radiation, and (ii) public or private groups having an expertise in the field of electronic product radiation;

(C) the reasonableness and technical feasibility of such standards as applied to a particular electronic product;

(D) the adaptability of such standards to the need for uniformity and reliability of testing and measuring procedures and equipment; and

(E) in the case of a component, or accessory described in paragraph (2)(B) of section 360hh of this title, the performance of such article in the manufactured or assembled product for which it is designed.

(2) The Secretary may prescribe different and individual performance standards, to the extent appropriate and feasible, for different electronic products so as to recognize their different operating characteristics and uses.

(3) The performance standards prescribed under this section shall not apply to any electronic product which is intended solely for export if (A) such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and (B) such product meets all the applicable requirements of the country to which such product is intended for export.

(4) The Secretary may by regulation amend or revoke any performance standard prescribed under this section.

(5) The Secretary may exempt from the provisions of this section any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

(b) Administrative procedure

The provisions of subchapter II of chapter 5 of title 5 (relating to the administrative procedure for rulemaking), and of chapter 7 of title 5 (relating to judicial review), shall apply with respect to any regulation prescribing, amending, or revoking any standard prescribed under this section.

(c) Publication in Federal Register

Each regulation prescribing, amending, or revoking a standard shall specify the date on which it shall take effect which, in the case of any regulation prescribing, or amending any standard, may not be sooner than one year or not later than two years after the date on which such regulation is issued, unless the Secretary finds, for good cause shown, that an earlier or later effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier or later date shall apply.

(d) Judicial review

(1) In a case of actual controversy as to the validity of any regulation issued under this section prescribing, amending, or revoking a performance standard, any person who will be adversely affected by such regulation when it is effective may at any time prior to the sixtieth day after such regulation is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such regulation. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based the regulation, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original regulation, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to review the regulation in accordance with chapter 7 of title 5 and to grant appropriate relief as provided in such chapter.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such regulation of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(5) Any action instituted under this subsection shall survive, notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not substitution for any other remedies provided by law.

(e) Availability of record

A certified copy of the transcript of the record and administrative proceedings under this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, exclusion of imports, or other proceeding arising under or in respect of this part irrespective of whether proceedings with respect to the regulation have previously been initiated or become final under this section.

(f) Technical Electronic Product Radiation Safety Standards Committee

(1)(A) The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this part referred to as the "Committee") which he shall consult before prescribing any standard under this section. The Committee shall be appointed by the Secretary, after consultation with public and private agencies concerned with the technical aspect of electronic product radiation safety, and shall be composed of fifteen members each of whom shall be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(i) Five members shall be selected from governmental agencies, including State and Federal Governments;

(ii) Five members shall be selected from the affected industries after consultation with industry representatives; and

(iii) Five members shall be selected from the general public, of which at least one shall be a representative of organized labor.

(B) The Committee may propose electronic product radiation safety standards to the Secretary for his consideration. All proceedings of the Committee shall be recorded and the record of each such proceeding shall be available for public inspection.

(2) Payments to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42 [1] shall not render members of the Committee officers or employees of the United States for any purpose.

(g) Review and evaluation

The Secretary shall review and evaluate on a continuing basis testing programs carried out by industry to assure the adequacy of safeguards against hazardous electronic product radiation and to assure that electronic products comply with standards prescribed under this section.

(h) Product certification

Every manufacturer of an electronic product to which is applicable a standard in effect under this section shall furnish to the distributor or dealer at the time of delivery of such product, in the form of a label or tag permanently affixed to such product or in such manner as approved by the Secretary, the certi-

[1] See References in Text note below.

fication that such product conforms to all applicable standards under this section. Such certification shall be based upon a test, in accordance with such standard, of the individual article to which it is attached or upon a testing program which is in accord with good manufacturing practice and which has not been disapproved by the Secretary (in such manner as he shall prescribe by regulation) on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this section.

(June 25, 1938, ch. 675, § 534, formerly act July 1, 1944, ch. 373, title III, § 534, formerly § 358, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1177; amended Oct. 30, 1970, Pub. L. 91-515, title VI, § 601(b)(2), (3), 84 Stat. 1311; renumbered § 534 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(B), (3), (4), 104 Stat. 4529, 4530.)

REFERENCES IN TEXT

Section 210 of title 42, referred to in subsec. (f)(2), was in the original "section 208 of this Act" and has been transiated as reading "section 208 of the Public Health Service Act" to reflect the probable intent of Congress and the transfer of this section from the Public Health Service Act by Pub. L. 101-629.

CODIFICATION

Section was classified to section 263f of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263f of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(1)(E). Pub. L. 101-629, § 19(a)(2)(B), substituted "section 360hh" for "section 263c".

Subsecs. (e), (f)(1)(A). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

1970—Subsec. (f)(2). Pub. L. 91-515 struck out provisions related to payment of compensation and travel expenses of members of the Committee who are not officers or employees of the United States, and substituted "to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42" for "under this subsection".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360ii, 360ll, 360mm, 360nn, 360oo, 360pp, 360ss of this title.

§ 360ll. Notification of defects in and repair or replacement of electronic products

(a) Notification; exemption

(1) Every manufacturer of electronic products who discovers that an electronic product produced, assembled, or imported by him has a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, or that an electronic product produced, assembled, or imported by him on or after the effective date of an applicable standard prescribed pursuant to section 360kk of this title fails to comply with such standard, shall immediately notify the Secretary of such defect or failure to comply if such product has left the place of manufacture and shall (except as authorized by paragraph (2)) with reasonable promptness furnish notification of such defect or failure to the persons (where known to the manufacturer) specified in subsection (b) of this section.

(2) If, in the opinion of such manufacturer, the defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he may, at the time of giving notice to the Secretary of such defect or failure to comply, apply to the Secretary for an exemption from the requirement of notice to the persons specified in subsection (b) of this section. If such application states reasonable grounds for such exemption, the Secretary shall afford such manufacturer an opportunity to present his views and evidence in support of the application, the burden of proof being on the manufacturer. If, after such presentation, the Secretary is satisfied that such defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he shall exempt such manufacturer from the requirement of notice to the persons specified in subsection (b) of this section and from the requirements of repair or replacement imposed by subsection (f) of this section.

(b) Method of notification

The notification (other than to the Secretary) required by paragraph (1) of subsection (a) of this section shall be accomplished—

(1) by certified mail to the first purchaser of such product for purposes other than resale, and to any subsequent transferee of such product; and

(2) by certified mail or other more expeditious means to the dealers or distributors of such manufacturer to whom such product was delivered.

(c) Requisite elements of notification

The notifications required by paragraph (1) of subsection (a) of this section shall contain a clear description of such defect or failure to comply with an applicable standard, an evaluation of the hazard reasonably related to such defect or fallure to comply, and a statement of the measures to be taken to repair such defect. In the case of a notification to a person referred to in subsection (b) of this section, the notification shall aiso advise the person of his rights under subsection (f) of this section.

(d) Copies to Secretary of communications by manufacturers to dealers or distributors regarding defects

Every manufacturer of electronic products shall furnish to the Secretary a true or representative copy of all notices, bulletins, and other communications to the dealers or distributors of such manufacturer or to purchasers (or subsequent transferees) of electronic products

of such manufacturer regarding any such defect in such product or any such failure to comply with a standard applicable to such product. The Secretary shall disclose to the public so much of the information contained in such notice or other information obtained under section 360nn of this title as he deems will assist in carrying out the purposes of this part, but he shall not disclose any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 unless he determines that it is necessary to carry out the purposes of this part.

(e) Notice from Secretary to manufacturer of defects or failure to comply with standards

If through testing, inspection, investigation, or research carried out pursuant to this part, or examination of reports submitted pursuant to section 360nn of this title, or otherwise, the Secretary determines that any electronic product—

(1) does not comply with an applicable standard prescribed pursuant to section 360kk of this title; or

(2) contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation;

he shall immediately notify the manufacturer of such product of such defect or failure to comply. The notice shall contain the findings of the Secretary and shall include all information upon which the findings are based. The Secretary shall afford such manufacturer an opportunity to present his views and evidence in support thereof, to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of such radiation hazard. If after such presentation by the manufacturer the Secretary determines that such product does not comply with an applicable standard prescribed pursuant to section 360kk of this title, or that it contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, the Secretary shall direct the manufacturer to furnish the notification specified in subsection (c) of this section to the persons specified in paragraphs (1) and (2) of subsection (b) of this section (where known to the manufacturer), unless the manufacturer has applied for an exemption from the requirement of such notification on the ground specified in paragraph (2) of subsection (a) of this section and the Secretary is satisfied that such noncompliance or defect is not such as to create a significant risk of injury, including genetic injury, to any person.

(f) Correction of defects

If any electronic product is found under subsection (a) or (e) of this section to fail to comply with an applicable standard prescribed under this part or to have a defect which relates to the safety of use of such product, and the notification specified in subsection (c) of this section is required to be furnished on account of such failure or defect, the manufacturer of such product shall (1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied, (2) replace such product with a like or equivalent product which complies with each applicable standard prescribed under this part and which has no defect relating to the safety of its use, or (3) make a refund of the cost of such product. The manufacturer shall take the action required by this subsection in such manner, and with respect to such persons, as the Secretary by regulations shall prescribe.

(g) Effective date

This section shall not apply to any electronic product that was manufactured before October 18, 1968.

(June 25, 1938, ch. 675, § 535, formerly act July 1, 1944, ch. 373, title III, § 535, formerly § 359, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1180; renumbered § 535 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(C), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263g of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263g of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(1). Pub. L. 101-629, § 19(a)(2)(C)(i), substituted "section 360kk" for "section 263f".

Subsec. (d). Pub. L. 101-629, § 19(a)(1)(B), (2)(C)(ii), substituted "section 360nn" for "section 263i" and "this part" for "this subpart" in two places.

Subsec. (e). Pub. L. 101-629, § 19(a)(1)(B), (2)(C), substituted "this part" for "this subpart" and "section 360nn" for "section 263i" in introductory provisions and "section 360kk" for "section 263f" in par. (1) and concluding provisions.

Subsec. (f). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" in two places.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360nn, 360oo of tbis title.

§ 360mm. Imports

(a) Refusal of admission to noncomplying electronic products

Any electronic product offered for importation into the United States which fails to comply with an applicable standard prescribed under this part, or to which is not affixed a certification in the form of a label or tag in conformity with section 360kk(h) of this title shall be refused admission into the United States. The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon the latter's request, samples of electronic

products which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may have a hearing before the Secretary of Health and Human Services. If it appears from an examination of such samples or otherwise that any electronic product fails to comply with applicable standards prescribed pursuant to section 360kk of this title, then, unless subsection (b) of this section applies and is complied with, (1) such electronic product shall be refused admission, and (2) the Secretary of the Treasury shall cause the destruction of such electronic product unless such article is exported, under regnlations prescribed by the Secretary of the Treasury, within 90 days after the date of notice of refusal of admission or within such additional time as may be permitted by such regulations.

(b) Bond

If it appears to the Secretary of Health and Human Services that any electronic product refused admission pursuant to subsection (a) of this section can be brought into compliance with applicable standards prescribed pursuant to section 360kk of this title, final determination as to admission of such electronic product may be deferred upon filing of timely written application by the owner or consignee and the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as the Secretary of Health and Human Services may by regulation prescribe. If such application is filed and such bond is executed the Secretary of Health and Human Services may, in accordance with rules prescribed by him, permit the applicant to perform such operations with respect to such electronic product as may be specified in the notice of permission.

(c) Liability of owner or consignee for expenses connected with refusal of admission

All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of operations provided for in subsection (b) of this section, and all expenses in connection with the storage, cartage, or labor with respect to any electronic product refused admission pursuant to subsection (a) of this section, shall be paid by the owner or consignee, and, in event of default, shall constitute a lien against any future importations made by such owner or consignee.

(d) Designation of agent for purposes of service

It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

(June 25, 1938, ch. 675, § 536, formerly act July 1, 1944, ch. 373, title III, § 536, formerly § 360, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1181; renumbered § 536 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(D), (3), (4), 104 Stat. 4529, 4530; June 16, 1992, Pub. L. 102-300, § 6(b)(1), 106 Stat. 240.)

CODIFICATION

Section was classified to section 263h of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1992—Subsecs. (a), (b). Pub. L. 102-300 substituted "Health and Human Services" for "Health, Education, and Welfare" wherever appearing.

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263h of Title 42, The Public Health and Welfare, as this section.

Subsec. (a). Pub. L. 101-629, § 19(a)(1)(B), (2)(D), substituted "this part" for "this subpart", "section 360kk(h)" for "section 263f(h)", and "section 360kk" for "section 263f".

Subsec. (b). Pub. L. 101-629, § 19(a)(2)(D), substituted "section 360kk" for "section 263f".

Subsec. (d). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" in two places.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360nn. Inspection, records, and reports

(a) Inspection of premises

If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times, any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 360kk(h) of this title are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon

which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this part and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 360*ll*(a)(2) or 360*ll*(e) of this title.

(h) Record keeping

Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this part and standards prescribed pursuant to this part and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to this part.

(c) Disclosure of technical data

Every manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out the purposes of this part. The Secretary is authorized to require the manufacturer to give such notification of such performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product, as he determines necessary to carry out the purposes of this part after consulting with the affected industry.

(d) Puhlic nature of reports

Accident and investigation reports made under this part by any officer, employee, or agent of the Secretary shall be available for use in any civil, criminal, or other judicial proceeding arising out of such accident. Any such officer, employee, or agent may be required to testify in such proceedings as to the facts developed in such investigations. Any such report shall be made available to the public in a manner which need not identify individuals. All reports on research projects, demonstration projects, and other related activities shall be public information.

(e) Trade secrets

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to subsectlon (a) or (b) of this section, which concerns any information which contains or relates to a trade secret or other matter referred to in sectlon 1905 of title 18, except that such information may be disclosed to other officers or employees of the Department and of other agencies concerned with carrying out this part or when relevant in any proceeding under this part. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

(f) Information required to identify and locate first purchasers of electronic products

The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this part and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 360*ll* of this title, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer, to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 360*ll* of this title, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefor for the purposes of section 360*ll* of this title, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 360*ll*(a) of this title.

(June 25, 1938, ch. 675, § 537, formerly act July 1, 1944, ch. 373, title III, § 537, formerly § 360A, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1182; renumbered § 537 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(E), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263i of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263l of Title 42, The Public Health and Welfare, as this section.

Subsec. (a). Pub. L. 101-629, § 19(a)(1)(B), (2)(E), substituted "section 360kk(h)" for "section 263f(h)", "this part" for "this subpart", and "section 360*ll*(a)(2) or 360*ll*(e)" for "section 263g(a)(2) or 263g(e)".

Subsecs. (b) to (e). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" wherever appearing.

Subsec. (f). Pub. L. 101-629, § 19(a)(1)(B), (2)(E)(ii), substituted "this part" for "this subpart", "section 360*ll*" for "section 263g" in three places, and "section 360*ll*(a)" for "section 263g(a)".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United

States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360*ll*, 360*oo* of this title.

§ 360*oo*. Prohibited acts

(a) It shall be unlawful—

(1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 360kk of this title;

(2) for any person to fail to furnish any notification or other material or information required by section 360*ll* or 360nn of this title; or to fail to comply with the requirements of section 360*ll*(f) of this title;

(3) for any person to fail or to refuse to establish or maintain records required by this part or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 360nn of this title;

(4) for any person to fail or to refuse to make any report required pursuant to section 360nn(b) of this title or to furnish or preserve any information required pursuant to section 360nn(f) of this title; or

(5) for any person (A) to fail to issue a certification as required by section 360kk(h) of this title, or (B) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 360kk(h) of this title or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.

(b) The Secretary may exempt any electronic product, or class thereof, from all or part of subsection (a) of this section, upon such conditions as he may find necessary to protect the public health or welfare, for the purpose of research, investigations, studies, demonstrations, or training, or for reasons of national security.

(June 25, 1938, ch. 675, § 538, formerly act July 1, 1944, ch. 373, title III, § 538, formerly § 360B, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1184; renumbered § 538 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(F), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263j of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263j of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(1). Pub. L. 101-629, § 19(a)(2)(F)(i), substituted "section 360kk" for "section 263f".

Subsec. (a)(2). Pub. L. 101-629, § 19(a)(2)(F)(ii), (iii), substituted "section 360*ll* or 360nn" for "section 263g or 263i" and "section 360*ll*(f)" for "section 263g(f)".

Subsec. (a)(3). Pub. L. 101-629, § 19(a)(1)(B), (2)(F)(iii), substituted "this part" for "this subpart" and "section 360nn" for "section 263i".

Subsec. (a)(4). Pub. L. 101-629, § 19(a)(2)(F)(iii), substituted "section 360nn(b)" for "section 263i(b)" and "section 360nn(f)" for "section 263i(f)".

Subsec. (a)(5). Pub. L. 101-629, § 19(a)(2)(F)(i), substituted "section 360kk(h)" for "section 263f(h)" in two places.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360pp of this title.

§ 360pp. Enforcement

(a) Jurisdiction of courts

The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of section 360*oo* of this title and to restrain dealers and distributors of electronic products from selling or otherwise disposing of electronic products which do not conform to an applicable standard prescribed pursuant to section 360kk of this title except when such products are disposed of by returning them to the distributor or manufacturer from whom they were obtained. The district courts of the United States shall also have jurisdiction in accordance with section 1355 of title 28 to enforce the provisions of subsection (b) of this section.

(b) Penalties

(1) Any person who violates section 360*oo* of this title shall be subject to a civil penalty of not more than $1,000. For purposes of this subsection, any such violation shall with respect to each electronic product involved, or with respect to each act or omission made unlawful by section 360*oo* of this title, constitute a separate violation, except that the maximum civil penalty imposed on any person under this subsection for any related series of violations shall not exceed $300,000.

(2) Any such civil penalty may on application be remitted or mitigated by the Secretary. In determining the amount of such penalty, or whether it should be remitted or mitigated and in what amount, the appropriateness of such penalty to the size of the business of the person charged and the gravity of the violation shall be considered. The amount of such penalty, when finally determined, may be deducted from any sums owing by the United States to the person charged.

(c) Venue; process

Actions under subsections (a) and (b) of this section may be brought in the district court of the United States for the district wherein any act or omission or transaction constituting the violation occurred, or in such court for the district where the defendant is found or transacts business, and process in such cases may be served in any other district of which the defendant is an inhabitant or wherever the defendant may be found.

(d) Warnings

Nothing in this part shall be construed as requiring the Secretary to report for the institution of proceedings minor violations of this part whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(e) Compliance with regulations

Except as provided in the first sentence of section 360ss of this title, compliance with this part or any regulations issued thereunder shall not relieve any person from liability at common law or under statutory law.

(f) Additional remedies

The remedies provided for in this part shall be in addition to and not in substitution for any other remedies provided by law.

(June 25, 1938, ch. 675, § 539, formerly act July 1, 1944, ch. 373, title III, § 539, formerly § 360C, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1184; renumbered § 539 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(G), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263k of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263k of Title 42, The Public Health and Welfare, as this section.

Subsec. (a). Pub. L. 101-629, § 19(a)(2)(G)(i), (ii), substituted "section 360*oo*" for "section 263j" and "section 360kk" for "section 263f".

Subsec. (b)(1). Pub. L. 101-629, § 19(a)(2)(G)(ii), substituted "section 360*oo*" for "section 263j" in two places.

Subsec. (d). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" in two places.

Subsec. (e). Pub. L. 101-629, § 19(a)(1)(B), (2)(G)(iii), substituted "section 360ss" for "section 263n" and "this part" for "this subpart".

Subsec. (f). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360qq. Annual report

(a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part for the preceding calendar year. Such report shall include—

(1) a thorough appraisal (including statistical analyses, estimates, and long-term projections) of the incidence of biological injury and effects, including genetic effects, to the population resulting from exposure to electronic product radiation, with a breakdown, insofar as practicable, among the various sources of such radiation;

(2) a list of Federal electronic product radiation control standards prescribed or in effect in such year, with identification of standards newly prescribed during such year;

(3) an evaluation of the degree of observance of applicable standards, including a list of enforcement actions, court decisions, and compromises of alleged violations by location and company name;

(4) a summary of outstanding problems confronting the adininistration of this part in order of priority;

(5) an analysis and evaluation of research activities completed as a result of Government and private sponsorship, and technological progress for safety achieved during such year;

(6) a list, with a brief statement of the issues, of completed or pending judicial actions under this part;

(7) the extent to which technical information was disseminated to the scientific, commercial, and labor community and consumer-oriented information was made available to the public; and

(8) the extent of cooperation between Government officials and representatives of industry and other interested parties in the implementation of this part including a log or summary of meetings held between Government officials and representatives of industry and other interested parties.

(b) The report required by subsection (a) of this section shall contain such recommendations for additional legislation as the Secretary deems necessary to promote cooperation among the several States in the improvement of electronic product radiation control and to strengthen the national electronic product radiation control program.

(June 25, 1938, ch. 675, § 540, formerly act July 1, 1944, ch. 373, title III, § 540, formerly § 360D, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1185; renumbered § 540 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263*l* of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263*l* of Title 42, The Public Health and Welfare, as this section.

Subsec. (a). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" wherever appearing.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, sec section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360rr. Federal-State cooperation

The Secretary is authorized (1) to accept from State and local authorities engaged in activities related to health or safety or consumer protection, on a reimbursable basis or otherwise, any assistance in the administration and

enforcement of this part which he may request and which they may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance, and (2) he may, for the purpose of conducting examinations, investigations, and inspections, commission any officer or employee of any such authority as an officer of the Department.

(June 25, 1938, ch. 675, § 541, formerly act July 1, 1944, ch. 373, title III, § 541, formerly § 360E, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1186; renumbered § 541 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263m of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263m of Title 42, The Public Health and Welfare, as this section.

Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360ss. State standards

Whenever any standard prescribed pursuant to section 360kk of this title with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard. Nothing in this part shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.

(June 25, 1938, ch. 675, § 542, formerly act July 1, 1944, ch. 373, title III, § 542, formerly § 360F, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1186; renumbered § 542 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(H), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263n of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263n of Title 42, The Public Health and Welfare, as this section.

Pub. L. 101-629, § 19(a)(1)(B), (2)(H), substituted "section 360kk" for "section 263f" and "this part" for "this subpart".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360pp of this title.

SUBCHAPTER VI—COSMETICS

§ 361. Adulterated cosmetics

A cosmetic shall be deemed to be aduiterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided,* That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

[*See main edition for text of* (b) *to* (d)]

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

(As amended Oct. 29, 1992, Pub. L. 102-571, title I, § 107(11), 106 Stat. 4499.)

CODIFICATION

Par. (a) of this section is set out in this supplement to correct error appearing in the main edition.

AMENDMENTS

1992—Par. (e). Pub. L. 102-571 substituted "379e(a)" for "376(a)".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 379e of this title.

§ 362. Misbranded cosmetics

A cosmetic shall be deemed to be misbranded—

[*See main edition for text of* (a)]

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small

packages shall be established, by regulations prescribed by the Secretary.

[*See main edition for text of (c) and (d)*]

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 361(a) of this title).

[*See main edition for text of (f)*]

(As amended Oct. 29, 1992, Pub. L. 102-571, title I, § 107(12), 106 Stat. 4499.)

CODIFICATION

Par. (b) of this section is set out in this supplement to correct error appearing in the main edition.

AMENDMENTS

1992—Par. (e). Pub. L. 102-571 substituted "379e" for "376".

SUBCHAPTER VII—GENERAL AUTHORITY

PART A—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings

[*See main edition for text of (a) to (d)*]

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

[*See main edition for text of (2) and (3); (f) and (g)*]

(As amended Nov. 8, 1990, Pub. L. 101-535, § 8, 104 Stat. 2365; June 16, 1992, Pub. L. 102-300, § 6(b)(1), 106 Stat. 240.)

AMENDMENTS

1992—Subsec. (b). Pub. L. 102-300, which directed the substitution of "Health and Human Services" for "Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. Previously, references to the Secretary of Health and Human Services were substituted for references to the Secretary of Agriculture pursuant to the provisions cited in the Change of Name and Transfer of Functions notes set out below.

1990—Subsec. (e)(1). Pub. L. 101-535 substituted "Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations)" for "Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title".

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Feod, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 346a, 352, 356, 357, 379e of this title; title 15 sections 1261, 1262, 1455, 1474.

§ 372. Examinations and investigations

[*See main edition for text*]

(As amended June 16, 1992, Pub. L. 102-300, § 6(b)(2), 106 Stat. 240.)

AMENDMENTS

1992—Subsec. (c). Pub. L. 102-300, which directed the amendment of subsec. (c) by striking out "of Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. Previously, references to the Department of Health and Human Services were substituted for references to the Department of Agriculture pursuant to the provisions cited in the Transfer of Functions note set out below.

§ 372a. Transferred

CODIFICATION

Section, act June 25, 1938, ch. 675, § 702A, formerly June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204, and amended, which related to examination of sea food, was renumbered section 706 of act June 25, 1938, by Pub. L. 102-571, title I, § 106(3), Oct. 29, 1992, 106 Stat. 4498, and transferred to section 376 of this title.

§ 375. Publicity

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360h of this title.

§ 376. Examination of sea food on request of packer; marking food with results; fees; penalties

The Secretary of Health and Human Services, upon application of any packer of any sea food

for shipment or sale within the jurisdiction of this chapter, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this chapter and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary of Health and Human Services for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Secretary is authorized to promulgate regulations governing the sanitary and other conditions under which the service herein provided shall be granted and maintained, and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine.

(June 25, 1938, ch. 675, § 706, formerly § 702A, formerly June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204; amended Aug. 27, 1935, ch. 739, 49 Stat. 671; June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; renumbered § 702A of act June 25, 1938, July 12, 1943, ch. 221, title II, 57 Stat. 500; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 16 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96-88, title V, § 509(b), 93 Stat. 695; June 16, 1992, Pub. L. 102-300, § 6(b)(2), 106 Stat. 240; renumbered § 706, Oct. 29, 1992, Pub. L. 102-571, title I, § 106(3), 106 Stat. 4498.)

CODIFICATION

Section was formerly classified to section 372a of this title prior to renumbering by Pub. L. 102-571.

Section, which formerly was not a part of the Federal Food, Drug, and Cosmetic Act, originally was classified to section 14a of this title. Section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that the section should remain in force and effect and be applicable to the provisions of this chapter. Act July 12, 1943, renumbered this section as 702A of the Federal Food, Drug, and Cosmetic Act.

PRIOR PROVISIONS

A prior section 376, act June 25, 1938, ch. 675, § 706, 52 Stat. 1058, as amended, which related to listing and certification of color additives for foods, drugs, devices, and cosmetics, was renumbered section 721 of act June 25, 1938, by Pub. L. 102-571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498, and transferred to section 379e of this title.

AMENDMENTS

1992—Pub. L. 102-300, which directed the amendment of the section by striking out "of Health, Education, and Welfare" wherever appearing, could not be executed because such words did not appear in the original statutory text. Previously, references to the Secretary of Health and Human Services were substituted for references to the Secretary of Agriculture pursuant to the provisions cited in the Change of Name and Transfer of Functions notes set out below.

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96-88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

§ 379b. Consolidated administrative and laboratory facility

(a) Authority

The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

(b) Awarding of contract

The Secretary shall solicit contract proposals under subsection (a) of this section from interested parties. In awarding contracts under such subsection, the Secretary shall review such proposals and give priority to those alternatives that are the most cost effective for the Federal Government and that allow for the use of donated land, federally owned property, or lease-purchase arrangements. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal Government over the duration of the contract, as compared to the Government purchase price including borrowing by the Secretary of the Treasury.

(c) Donations

In carrying out this section, the Secretary shall have the power, in connection with real property, buildings, and facilities, to accept on behalf of the Food and Drug Administration gifts or donations of services or property, real or personal, as the Secretary determines to be necessary.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section $100,000,000 for fiscal year 1991, and such sums as may be necessary for each of the subsequent fiscal years, to remain available until expended.

(June 25, 1938, ch. 675, § 710, as added Nov. 28, 1990, Pub. L. 101-635, title I, § 101, 104 Stat. 4583.)

§ 379c. Transferred

CODIFICATION

Section, act June 25, 1938, ch. 675, § 711, as added Nov. 28, 1990, Pub. L. 101-635, title II, § 201, 104 Stat. 4584, which related to recovery and retention of fees for freedom of information requests, was renumbered section 731 of act June 25, 1938, by Pub. L. 102-571, title I, § 106(6), Oct. 29, 1992, 106 Stat. 4499, and transferred to section 379f of this title.

§ 379d. Automation of Food and Drug Administration

(a) In general

The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this chapter.

(b) Authorization of appropriations

There are authorized to be appropriated each fiscal year such sums as are necessary to carry out this section.

(June 25, 1938, ch. 675, § 711, formerly § 712, as added Nov. 28, 1990, Pub. L. 101-635, title IV, § 401, 104 Stat. 4585; renumbered § 711, Oct. 29, 1992, Pub. L. 102-571, title I, § 106(3), 106 Stat. 4498.)

PRIOR PROVISIONS

A prior section 711 of act June 25, 1938, was renumbered section 731 by Pub. L. 102-571 and is classified to section 379f of this title.

PART B—COLORS

§ 379e. Listing and certification of color additives for foods, drugs, devices, and cosmetics

(a) Unsafe color additives

A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics, be deemed unsafe for the purposes of the application of section 342(c), 351(a)(4), or 361(e) of this title, as the case may be, unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c) of this section, for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) of this section with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 342(a) of this title if such article is a food, or within the meaning of section 361(a) of this title if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 361(a) of this title). A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject to this section.

(b) Listing of colors; regulations; issuance, amendment or repeal; referral to advisory committee; report and recommendations; appointment and compensation of advisory committee

(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, or devices, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2)(A) Such regulations may list any color additive for use generally in or on food, or in or on drugs or devices, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from

the term "food additive" because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 321(s) of this title.

(5)(A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive;

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug or device, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal: *Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d) of this section) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

(C)(i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 371(e) of this title if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

(iii) Where—

(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of any advisory committee established under this chapter, while attending conferences or meetings of their committees or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS-18 of the General Schedule, including traveltime; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) [1] of title 5 for persons in the Government service employed intermittently. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this chapter or would otherwise resuit in misbranding or adulteration within the ineaning of thls chapter.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for ail the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate ailowable safe tolerance for such additive or additives shail be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various nses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

(c) Certification of colors

The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batehes of color additives listed pursuant to subsection (b) of this section and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided,* That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

(d) Procedure for issuance, amendment, or repeal of regulations

The provisions of section 371(e), (f), and (g) of thls title shall, subject to the provisions of subparagraph (C) of subsection (b)(5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcrlpts of the record of such proceedings in other proceedings, except that—

(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 371(e) of this title) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary ınay (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not ınore than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investlgate the petition;

(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committoe appointed pursuant to subparagraph (D) of subsection

[1] See References in Text note below.

(b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 556(d) of title 5. The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 348(f)(2) of this title; and

(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 348(g) of this title.

(e) Fees

The admitting to listing and certification of color additives, in accordance with regulations prescribed under this chapter, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

(f) Exemptions

The Secretary shall by regulations (issued without regard to subsection (d) of this section) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or device, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

(June 25, 1938, ch. 675, § 721, formerly § 706, 52 Stat. 1058; July 12, 1960, Pub. L. 86-618, title I, § 103(b), 74 Stat. 399; Oct. 10, 1962, Pub. L. 87-781, title I, § 104(f)(2), 76 Stat. 785; Oct. 30, 1970, Pub. L. 91-515, title VI, § 601(d)(2), 84 Stat. 1311; May 28, 1976, Pub. L. 94-295, § 9(a), 90 Stat. 583; Oct. 17, 1979, Pub. L. 96-88, title V, § 509(b), 93 Stat. 695; June 16, 1992, Pub. L. 102-300, § 6(b)(2), 106 Stat. 240; renumbered § 721, Oct. 29, 1992, Pub. L. 102-571, title I, § 106(4), 106 Stat. 4498.)

REFERENCES IN TEXT

Section 5703 of title 5, referred to in subsec. (b)(5)(D), was amended generally by Pub. L. 94-22, § 4, May 19, 1975, 89 Stat. 85, and, as so amended, does not contain a subsec. (b).

CODIFICATION

Section was formerly classified to section 376 of this title prior to renumbering by Pub. L. 102-571.

In subsec. (d)(2), "section 556(d) of title 5" substituted for "section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c))" on authority of Pub. L. 89-554, § 7(b), Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

1992—Subsec. (b)(5)(C)(i). Pub. L. 102-300 struck out "of Health, Education, and Welfare" after "representatives of the Department".

1976—Subsec. (a). Pub. L. 94-295, § 9(a)(2), (3), inserted reference to devices and inserted provisions directing that color additives for use in or on devices be subject to this section only if the color additives come in direct contact with the body of man or other animals for a significant period of time and authorizing the Secretary to designate by regulation the uses of color additives in or on devices which are subject to this section.

Subsec. (b). Pub. L. 94-295, § 9(a)(1), (2), substituted "drug or device" for "drug" and "drugs or devices" for "drugs" wherever appearing.

Subsec. (f). Pub. L. 94-295, § 9(a)(1), substituted "drug or device" for "drug".

1970—Subsec. (b)(5)(D). Pub. L. 91-515 substituted provisions authorizing members of an advisory committee to receive compensation at rates fixed by the Secretary, with a specific maximum amount, and travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of Title 5, for provisions authorizing such members to receive as compensation a reasonable per diem for time actually spent on committee work, and necessary traveling and subsistence expenses while serving away from their places of residence.

1962—Subsec. (b)(5)(B). Pub. L. 87-781 provided that clause (i) of this subparagraph shall not apply to a color additive in feed of animals raised for food production, if under the conditions of use specified in proposed labeling, and which conditions are reasonably certain to be followed in practice, such additive will not adversely affect the animals and no residue will be found in any edible portion of such animal after slaughter or in any food from the living animal.

1960—Pub. L. 86-618 amended section generally. Prior to amendment, section read as follows: "The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this chapter, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes."

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87-781 effective Oct. 10, 1962, see section 107 of Pub. L. 87-781, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Title II of Pub. L. 86-618 provided that:

"SEC. 201. [DEFINITIONS.] As used in this title, the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act [this chapter]; the term 'enactment date' means the date of enactment of this Act [July 12, 1960]; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

"SEC. 202. [EFFECTIVE DATE.] This Act [amending this section and sections 321, 331, 333, 342, 343, 346, 351, 352, 361, 362, and 371 of this title and repealing sections 354 and 364 of this title] shall, subject to the provisions of section 203, take effect on the enactment date [July 12, 1960].

"SEC. 203. [PROVISIONAL LISTINGS OF COMMERCIALLY ESTABLISHED COLORS.] (a)(1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A

provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 [now 721] of the basic Act, [this section], whichever date first occurs.

"(2) For the purposes of this section, the term 'closing date' means (A) the last day of the two and one-half year period beginning on the enactment date [July 12, 1960] or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or decmed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 [now 721] of the hasic Act [this section]. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a fallure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

"(b) Subject to the other provisions of this seetion—

"(1) any color additive which, on the day preceding the enactment date [July 12, 1960], was listed and certifiable for any use or uses under seetion 406(b), 504, or 604 [section 346(b), 354, or 364 of this title], or under the third proviso of section 402(c) [section 342(c) of this title], of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date [July 12, 1960], and

"(2) any color additive which was commercially used or sold prior to the enactment date [July 12, 1960] for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date [July 12, 1960], was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shail, beginning on the enactment datc [July 12, 1960], be deemed to be provisionally listcd under this section as a color additive for such use or uses.

"(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additlve for any use for which it was listed, and for which a bateh or batehes of such material had been certifled, under section 406(b), 504, or 604 of the basic Act [section 346(b), 354, or 364 of this title] prior to the enactment date [July 12, 1960], although such color was no longer listed and certifiable for such use under such sectlons on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

"(d)(1) The Secretary shall, by regulations issued or amended from time to time under this section—

"(A) insofar as practicable promulgatc and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shail, in any proceoding under the basic Act, be conclusive evidence that such provisional listing is in effect;

"(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

"(C) provide, with respect to particuiar uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 [now 721] of the basic Act [this section];

"(D) provide for the certification of batehes of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b)(2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

"(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

"(2)(A) Except as provided in subparagraph (C) of this paragraph, regulations under this sectlon shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act [subsec. (e) of this section], but for the purposes of the application of section 706(e) [now 721(e)] of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706 [now 721, this section]. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date [July 12, 1960] were in effect pursuant to section 706 [now 721] of the basic Act [this section], shall be deemed to be regulations under such section 706 [now 721, this section] as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such seetion 706 [now 721] as in effect prior to the enactment date [July 12, 1960] shall be available for the purposes specified in such section 706 [now 721, this section] as so amended.

"(B) If the Secretary, by regulation—

"(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1)(E) of this subsection; or

"(ii) has, pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affectcd by such action may, prior to the expiration of the period speeifled in clause (A) of subsection (a)(2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shail contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistcnt with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present

their views thereon orally or in writing, act upon such proposal by published order.

"(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make iess restrictive any other iimitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act [section 371(f) of this title] except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

"(D) On and after the enactment date [July 12, 1960], regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 [now 721] of the basic Act [this section]. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706(b) or (c) [now 721(b), (c)] of the basic Act [subsec. (b) or (c) of this section].

"(3) For the purpose of enabling the Secretary to carry out his functions under paragraphs (1)(A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act [July 12, 1960], afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1)(A), or for determining the prevailing level or levels of use thereof prior to the enactment date [July 12, 1960] with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1)(C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

"SEC. 204. [EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS INSPECTION ACTS.] Nothing in this Act [amending this section and sections 321, 331, 333, 342, 343, 346, 351, 352, 361, 362, and 371 of this title and repealing sections 354 and 364 of this title] shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following) [see section 601 et seq. of this title] or the Poultry Products Inspection Act (21 U.S.C. 451 and the following)."

EFFECTIVE DATE; ACCELERATION

This section was made "immediately effective" by act May 2, 1939, ch. 107, title I, § 1, 53 Stat. 631.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Empioyees.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Titie 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 343, 346a, 351, 352, 360j, 361, 362, 453, 601, 1033 of this title.

PART C—FEES

SUBPART 1—FREEDOM OF INFORMATION FEES

§ 379f. Recovery and retention of fees for freedom of information requests

(a) In general

The Secretary, acting through the Commissioner of Food and Drugs, may—

(1) set and charge fees, in accordance with section 552(a)(4)(A) of title 5, to recover all reasonable costs incurred in processing requests made under section 552 of title 5 for records obtained or created under this chapter or any other Federal law for which responsibillty for administratlon has been delegated to the Commissioner by the Secretary;

(2) retain all fees charged for such requests; and

(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section.

(b) Use of fees

The Secretary and the Commissioner of Food and Drugs shall not use fees received under this sectlon for any purpose other than funding the processing of requests described in subsection (a)(1) of this section. Such fees shall not be used to reduce the amount of funds made to carry out other provislons of this chapter.

(c) Waiver of fees

Nothing in this section shall supersede the right of a requester to obtain a waiver of fees pursuant to section 552(a)(4)(A) of title 5.

(June 25, 1938, ch. 675, § 731, formerly § 711, as added Nov. 28, 1990, Pub. L. 101-635, title II, § 201, 104 Stat. 4584; renumbered § 731, Oct. 29, 1992, Pub. L. 102-571, title I, § 106(6), 106 Stat. 4499.)

CODIFICATION

Section was formerly classified to section 379c of this title prior to renumbering by Pub. L. 102-571.

SUBPART 2—FEES RELATING TO DRUGS

§ 379g. Definitions

For purposes of this part:

(1) The term "human drug application" means an application for—

(A) approval of a new drug submitted under section 355(b)(1) of this title,

(B) approval of a new drug submitted under section 355(b)(2) of this title after September 30, 1992, which requests approval of—

(i) a molecular entity which is an active ingredient (including any salt or ester of an active ingredient), or

(ii) an indication for a use,

that had not been approved under an application submitted under section 355(b) of this title,

(C) initial certification or initial approval of an antibiotic drug under section 357 of this title, or

(D) licensure of a biological product under section 262 of title 42.

Such term does not include a supplement to such an application, does not include an application with respect to whole blood or a blood component for transfusion, does not include an application with respect to a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 262 of title 42, and does not include an application with respect to a large volume parenteral drug product approved before September 1, 1992.

(2) The term "supplement" means a request to the Secretary to approve a change in a human drug application which has been approved.

(3) The term "prescription drug product" means a specific strength or potency of a drug in final dosage form—

(A) for which a human drug application has been approved, and

(B) which may be dispensed only under prescription pursuant to section 353(b) of this title.

Such term does not include whole blood or a blood component for transfusion, does not include a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 262 of title 42, and does not include a large volume parenteral drug product approved before September 1, 1992.

(4) The term "final dosage form" means, with respect to a prescription drug product, a finished dosage form which is approved for administration to a patient without further manufacturing.

(5) The term "prescription drug establishment" means a foreign or domestic place of business which is—

(A) at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more prescription drug products are manufactured in final dosage form, and

(B) under the management of a person that is listed as the applicant in a human drug application for a prescription drug product with respect to at least one such product.

For purposes of this paragraph, the term "manufactured" does not include packaging.

(6) The term "process for the review of human drug applications" means the following activities of the Secretary with respect to the review of human drug applications and supplements:

(A) The activities necessary for the review of human drug applications and supplements.

(B) The issuance of action letters which approve human drug applications or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of prescription drug establishments and other facilities undertaken as part of the Secretary's review of pending human drug applications and supplements.

(D) Activities necessary for the review of applications for licensure of establishments subject to section 262 of title 42 and for the release of lots of biologics under such section.

(E) Monitoring of research conducted in connection with the review of human drug applications.

(7) The term "costs of resources allocated for the process for the review of human drug applications" means the expenses incurred in connection with the process for the review of human drug applications for—

(A) officers and employees of the Food and Drug Administration, employees under contract with the Food and Drug Administration who work in facilities owned or leased for the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees,

(B) management of information, and the acquisition, maintenance, and repair of computer resources,

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

(D) collecting fees under section 379h of this title and accounting for resources allocated for the review of human drug applications and supplements.

(8) The term "adjustment factor" applicable to a fiscal year is the lower of—

(A) the Consumer Price Index for all urban consumers (all items; United States city average) for August of the preceding

fiscal year divided by such Index for August 1992, or

(B) the total of discretionary budget authority provided for programs in the domestic category for the immediately preceding fiscal year (as reported in the Office of Management and Budget sequestration preview report, if available, required under section 254(d) of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 904(d)]) divided by such budget authority for fiscal year 1992 (as reported in the Office of Management and Budget final sequestration report submitted after the end of the 102d Congress, 2d Session).

The terms "budget authority" and "category" in subparagraph (B) are as defined in the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.], as in effect as of September 1, 1992.

(June 25, 1938, ch. 675, § 735, as added Oct. 29, 1992, Pub. L. 102-571, title I, § 103, 106 Stat. 4491.)

TERMINATION OF SECTION

For termination of section by section 105 of Pub. L. 102-571, see Termination Date note below.

REFERENCES IN TEXT

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in par. (8), is title II of Pub. L. 99-177, Dec. 12, 1985, 99 Stat. 1038, as amended, which enacted chapter 20 (§ 900 et seq.) and sections 654 to 656 of Title 2, The Congress, amended sections 602, 622, 631 to 642, and 651 to 653 of Title 2, sections 1104 to 1106, and 1109 of Title 31, Money and Finance, and section 911 of Title 42, The Public Health and Welfare, repealed section 661 of Title 2, enacted provisions set out as notes under section 900 of Title 2 and section 911 of Title 42, and amended provisions set out as a note under section 621 of Title 2. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

TERMINATION DATE

Section 105 of Pub. L. 102-571 provided that: "The amendments made by section 103 [enacting this subpart] shall not be in effect after October 1, 1997 and section 104 [enacting provisions set out as a note below] shall not be in effect after 120 days after such date."

CONGRESSIONAL FINDINGS CONCERNING PRESCRIPTION DRUG USER FEES

Section 102 of title I of Pub. L. 102-571 provided that: "The Congress finds that—

"(1) prompt approval of safe and effective new drugs is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

"(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications; and

"(3) the fees authorized by this title [see Short Title of 1992 Amendment note, set out under section 301 of this title] will be dedicated toward expediting the review of human drug applications as set forth in the goals identified in the letters of September 14, 1992, and September 21, 1992, from the Commissioner of Food and Drugs to the Chairman of the Energy and Commerce Committee of the House of Representatives and the Chairman of the Labor and Human Resources Committee of the Senate, as set forth at 138 Cong. Rec. H9099-H9100 (daily ed. September 22, 1992)."

ANNUAL REPORTS

Section 104 of Pub. L. 102-571 provided that:

"(a) FIRST REPORT.—Within 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], the Secretary of Health and Human Services shall submit a report stating the Food and Drug Administration's progress in achieving the goals identified in section 102(3) of this Act [set out as a note above] during such fiscal year and that agency's future plans for meeting such goals.

"(b) SECOND REPORT.—Within 120 days after the end of each fiscal year during which such fees are collected, the Secretary of Health and Human Services shall submit a report on the implementation of the authority for such fees during such fiscal year and on the use the Food and Drug Administration made of the fees collected during such fiscal year for which the report is made.

"(c) COMMITTEES.—The reports described in subsections (a) and (b) shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate."

ANIMAL DRUG USER FEE STUDY

Section 108 of Pub. L. 102-571 provided that:

"(a) STUDY.—The Secretary, in consultation with manufacturers of animal drug products and other interested persons, shall undertake a study to evaluate whether, and under what conditions, to impose user fees to supplement appropriated funds in order to improve the process of reviewing applications (including abbreviated and supplemental applications) for new animal drugs under section 512 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b]. The study shall include—

"(1) an assessment of the overall review process for animal drugs at the Center for Veterinary Medicine, including the number of applications received, and the average times for interim and final decisions on each type of application,

"(2) the current allocation of funds to the animal drug review process,

"(3) recommendations for goals for decision making times on applications submitted to the Center for Veterinary Medicine and for additional resources required to meet the goals, and

"(4) recommendations for supplementing the resources for the animal drug review process through user fees.

"(b) COMPLETION.—The results of the study required by subsection (a) shall be presented no later than January 4, 1994, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 379h of this title.

§ 379h. Authority to assess and use drug fees

(a) Types of fees

Beginning in fiscal year 1993, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Human drug application and supplement fee

(A) In general

Each person that submits, on or after September 1, 1992, a human drug application or a supplement shall be subject to a fee as follows:

(i) A fee established in subsection (b) of this section for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established in subsection (b) of this section for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required.

(B) Payment scbedule

(i) First payment

50 percent of the fee required by subparagraph (A) shall be due upon submission of the application or supplement.

(ii) Final payment

The remaining 50 percent of the fee required by subparagraph (A) shall be due upon—

(I) the expiration of 30 days from the date the Secretary sends to the applicant a letter designated by the Secretary as an action letter described in section 379g(6)(B) of this title, or

(II) the withdrawal of the application or supplement after it is filed unless the Secretary waives the fee or a portion of the fee because no substantial work was performed on such application or supplement after it was filed.

The designation under subclause (I) or the waiver under subclause (II) shall be solely in the discretion of the Secretary and shall not be reviewable.

(C) Exception for previously filed application or supplement

If a human drug application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) Refund of fee if application not accepted for filing

The Secretary shall refund 50 percent of the fee paid under subparagraph (B)(i) for any application or supplement which is not accepted for filing.

(2) Prescription drug establisbment fee

Each person that—

(A) owns a prescription drug establishment, at which is manufactured at least 1 prescription drug product which is not the, or not the same as a, product approved under an application filed under section 355(b)(2) or 355(j) of this title, and

(B) after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall be subject to the annual fee established in subsection (b) of this section for each such establishment, payable on or before January 31 of each year.

(3) Prescription drug product fee

(A) In general

Except as provided in subparagraph (B), each person—

(i) who is named as the applicant in a human drug application for a prescription drug product which is listed under section 360 of this title, and

(ii) who, after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall pay for each such prescription drug product the annual fee established in subsection (b) of this section. Such fee shall be payable at the time of the first such listing of such product in each calendar year. Such fee shall be paid only once each year for each listed prescription drug product irrespective of the number of times such product is listed under section 360 of this title.

(B) Exception

The listing of a prescription drug product under section 360 of this title shall not require the person who listed such product to pay the fee prescribed by subparagraph (A) if such product is the same product as a product approved under an application filed under section 355(b)(2) or 355(j) of this title.

(b) Fee amounts

(1) Schedule

Except as provided in paragraph (2) and subsections (c), (d), (f), and (g) of this section, the fees required under subsection (a) of this section shall be paid in accordance with the following schedule:

	Fiscal Year 1993	Fiscal Year 1994	Fiscal Year 1995	Fiscal Year 1996	Fiscal Year 1997
Drug application fee:					
Subsection (a)(1)(A)(i) fee	$100,000	$150,000	$208,000	$217,000	$233,000
Subsection (a)(1)(A)(ii) fee	$50,000	$75,000	$104,000	$108,000	$116,000
Fee revenue	$12,000,000	$18,000,000	$25,000,000	$26,000,000	$28,000,000

	Fiscal Year 1993	Fiscal Year 1994	Fiscal Year 1995	Fiscal Year 1996	Fiscal Year 1997
Annual establishment fee:					
Fee per establishment	$60,000	$88,000	$126,000	$131,000	$138,000
Fee revenue	$12,000,000	$18,000,000	$25,000,000	$26,000,000	$28,000,000
Annual product fee:					
Fee per product	$6,000	$9,000	$12,500	$13,000	$14,000
Fee revenue	$12,000,000	$18,000,000	$25,000,000	$26,000,000	$28,000,000
Total fee revenues	$36,000,000	$54,000,000	$75,000,000	$78,000,000	$84,000,000

(2) Small business exception

Any business which has fewer than 500 employees, including employees of affiliates, and which does not have a prescription drug product introduced or delivered for introduction into interstate commerce shall pay one-half the amount of the fee for human drug applications it submits and shall pay the entire amount of the fee for supplements it submits. Such a business shall not be required to pay any portion of any fee required under subsection (a)(1)(A) of this section until 1 year after the date of the submission of the application involved. For purposes of this paragraph, one business is an affiliate of another business when, directly or indirectly, one business controls, or has the power to control, the other business or a third party controls, or has the power to control, both businesses.

(c) Increases and adjustments

(1) Revenue increase

The total fee revenues established by the schedule in subsection (b)(1) of this section shall be increased by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

(A) the total percentage increase that occurred during the preceding fiscal year in the Consumer Price Index for all urban consumers (all items; U.S. city average), or

(B) the total percentage increase for such fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

(2) Annual fee adjustment

Subject to the amount appropriated for a fiscal year under subsection (g) of this section, the Secretary shall, within 60 days after the end of each fiscal year beginning after October 1, 1992, adjust the fees established by the schedule in subsection (b)(1) of this section for the following fiscal year to achieve the total fee revenues, as may be increased under paragraph (1). Such fees shall be adjusted under this paragraph to maintain the proportions established in such schedule.

(3) Limit

The total amount of fees charged, as adjusted under paragraph (2), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

(d) Fee waiver or reduction

The Secretary shall grant a waiver from or a reduction of 1 or more fees under subsection (a) of this section where the Secretary finds that—

(1) such waiver or reduction is necessary to protect the public health,

(2) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

(3) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or

(4) assessment of the fee for an application or a supplement filed under section 355(b)(1) of this title pertaining to a drug containing an active ingredient would be inequitable because an application for a product containing the same active ingredient filed by another person under section 355(b)(2) of this title could not be assessed fees under subsection (a)(1) of this section.

In making the finding in paragraph (3), the Secretary may use standard costs.

(e) Effect of failure to pay fees

A human drug application or supplement submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

(f) Assessment of fees

(1) Limitation

Fees may not be assessed under subsection (a) of this section for a fiscal year beginning after fiscal year 1993 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1992 multiplied by the adjustment factor applicable to the fiscal year involved.

(2) Authority

If the Secretary does not assess fees under subsection (a) of this section during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for human drug ap-

plications and supplements, prescription drug establishments, and prescription drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) of this section relating to the date fees are to be paid.

(g) Crediting and availability of fees

(1) In general

Fees collected for a fiscal year pursuant to subsection (a) of this section shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation.

(2) Collections and appropriation acts

The fees authorized by this section—

(A) shall be collected in each fiscal year in an amount equal to the amount specified in appropriation Acts for such fiscal year, and

(B) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs for fiscal year 1992 multiplied by the adjustment factor.

(3) Authorization of appropriations

There are authorized to be appropriated for fees under this section—

(A) $36,000,000 for fiscal year 1993,
(B) $54,000,000 for fiscal year 1994,
(C) $75,000,000 for fiscal year 1995,
(D) $78,000,000 for fiscal year 1996, and
(E) $84,000,000 for fiscal year 1997,

as adjusted to reflect increases in the total fee revenues made under subsection (c)(1) of this section.

(h) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) of this section within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(i) Construction

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(June 25, 1938, ch. 675, § 736, as added Oct. 29, 1992, Pub. L. 102-571, title I, § 103, 106 Stat. 4494.)

TERMINATION OF SECTION

For termination of section by section 105 of Pub. L. 102-571, see Termination Date note below.

TERMINATION DATE

Section not in effect after Oct. 1, 1997, see section 105 of Pub. L. 102-571, set out as a note under section 379g of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 379g of this title.

SUBCHAPTER VIII—IMPORTS AND EXPORTS

§ 381. Imports and exports

(a) Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 360 of this title and shall request that if any drugs and devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs and devices be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 360j(f) of this title, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 355 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph [1] shall not

[1] So in original. Probably should be "subsection".

be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

(b) Disposition of refused articles

Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this chapter or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary of Health and Human Services may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary of Health and Human Services, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

[*See main edition for text of* (c)]

(d) Reimportation

(1) Except as provided in paragraph (2), no drug subject to section 353(b) of this title which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

[*See main edition for text of* (2); (e)]

(As amended June 16, 1992, Pub. L. 102-300, § 6(b)(1), 106 Stat. 240; Aug. 26, 1992, Pub. L. 102-353, § 5, 106 Stat. 943.)

AMENDMENTS

1992—Subsecs. (a), (b). Pub. L. 102-300, which directed the substitution of "Health and Human Services" for "Health, Education, and Welfare" wherever appearing, was executed in second sentence of subsec. (a), but could not be executed in first sentence of subsec. (a) or in subsec. (b) because such words did not appear in original statutory text. Previously, references to the Secretary of Health and Human Services were substituted for references to the Secretary of Agriculture pursuant to provisions cited in Change of Name and Transfer of Functions notes set out below.

Subsec. (d)(1). Pub. L. 102-353 substituted "manufacturer of" for "person who manufactured".

§ 382. Exports of certain unapproved products

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title; title 42 section 262.

§ 383. Office of International Relations

(a) There is established in the Department of Health and Human Services an Office of International Relations.

(b) In carrying out the functions of the office under subsection (a) of this section, the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this chapter. In such agreements, the Secretary shall encourage the mutual recognition of—

(1) good manufacturing practice regulations promulgated under section 360j(f) of this title, and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

(June 25, 1938, ch. 675, § 803, as added Nov. 28, 1990, Pub. L. 101-629, § 15(a), 104 Stat. 4525.)

REPORT ON ACTIVITIES OF OFFICE OF INTERNATIONAL RELATIONS

Section 15(b) of Pub. L. 101-629 provided that: "Not later than 2 years after the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report on the activities of the Office of International Relations under section 803 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 383], added by subsection (a)."

SUBCHAPTER IX—MISCELLANEOUS

§ 393. Food and Drug Administration

CODIFICATION

Another section 903 of the Federal Food, Drug, and Cosmetic Act is classified to section 394 of this title.

MANAGEMENT ACTIVITIES STUDY

Pub. L. 102-571, title II, § 205, Oct. 29, 1992, 106 Stat. 4502, provided that:

"(a) STUDY.—The Comptroller General shall conduct a study of the management of activities of the Food and Drug Administration that are related to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.

"(b) CONTENTS.—In conducting the study, the Comptroller General shall examine, with respect to such activities—

"(1) the means by which the Food and Drug Administration makes a determination that a substance poses a risk to public health and safety that justifies the expenditure of resources by the agency;

"(2) the means by which the Food and Drug Administration makes a determination that a substance is adulterated, misbranded, or improperly manufactured;

"(3) the means by which the Food and Drug Administration makes a determination relating to the quantitative management of the agency response to specific issues, in order to adjust the efforts of the agency to be commensurate with the severity of the problem addressed by the agency;

"(4) the approach by which the Food and Drug Administration determines the adequacy of proof re-

lated to the risk posed by, or the safety of, a substance, and the adequacy of such approach; and

"(5) the relationship between—

"(A)(i) the number of hours devoted by Food and Drug Administration personnel, and the expertise of such personnel, in conducting such activities;

"(ii) the cost of conducting such activities; and

"(iii) the cost to manufacturers of such supplements to achieve compliance with such activities; and

"(B)(i) the level of risk suspected to be posed by such supplements; and

"(ii) the level of risk determined to be posed by such supplements.

"(c) APPROACH.—In conducting the study, the Comptroller General shall analyze the current practices of the Food and Drug Administration and the practices of the agency within the 5 years prior to the date of enactment of this Act [Oct. 29, 1992].

"(d) ANALYSIS.—In conducting the study, the Comptroller General shall—

"(1) determine the relative proportion of resources devoted to Food and Drug Administration regulatory and enforcement activities that are related to—

"(A) dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances;

"(B) food additives that are not such dietary supplements;

"(C) foods that are not such dietary supplements;

"(D) drugs that are not such dietary supplements, and devices; or

"(E) cosmetics; and

"(2) determine, with respect to such supplements, with respect te food additives, and with respect to foods, the proportion of the resources devoted to such regulatory and enforcement activities that are used to—

"(A) determine whether a substance is misbranded;

"(B) determine whether an improper manufacturing practice occurred during the manufacturing of a substance;

"(C) determine whether a substance is unsafe; and

"(D) determine whether a substance is adulterated or otherwise in violation of the Federal Food, Drug, and Cosmetic Act [this chapter] (other than by making a determination described in subparagraph (A), (B), or (C)).

"(e) REPORTS.—

"(1) INTERIM REPORT.—

"(A) IN GENERAL.—Not later than 6 months after the date of enactment of this Act [Oct. 29, 1992], the Comptroller General shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an interim report containing the findings resulting from the study and the recommendations described in subparagraph (B).

"(B) RECOMMENDATIONS.—Such report shall include the recommendations of the Comptroller General for administrative reform, including recommendations regarding opportunities for encouraging economy and efficiency through the appropriate targeting of problems, managing resources appropriately, and making adequate determinations of risk or safety, in carrying out activities related to such supplements.

"(2) FINAL REPORT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of this Act [Oct. 29, 1992], the Comptroller General shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a final report containing the findings resulting from the study and the recommendations deseribed in subparagraph (B).

"(B) RECOMMENDATIONS.—Such report shall contain the recommendations described in paragraph (1)(B)."

§ 394. Scientific review groups

Without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

(1) establish such technical and scientific review groups as are needed to carry out the functions of the Food and Drug Administration (including functions prescribed under this chapter); and

(2) appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(June 25, 1938, ch. 675, § 903, as added Nov. 28, 1990, Pub. L. 101-635, title III, § 301, 104 Stat. 4584.)

REFERENCES IN TEXT

The provisions of title 5 governing appointments in the competitive service, referred to in text, are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

CODIFICATION

Another section 903 of the Federal Food, Drug, and Cosmetic Act is classified to section 393 of this title.

CHAPTER 10—POULTRY AND POULTRY PRODUCTS INSPECTION

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in section 321 of this title; title 7 sections 138f, 6519.

§ 453. Definitions

For purposes of this chapter—

[*See main edition for text of* (*a*) *to* (*f*)]

(g) The term "adulterated" shall apply to any poultry product under one or more of the following circumstances:

[*See main edition for text of* (*1*)]

(2) [*See main edition for text of* (*A*) *to* (*C*)] (D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: *Provided*, That an article which is not otherwise deemed adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in official establishments;

[*See main edition for text of* (*3*) *to* (*8*); (*h*) *to* (*bb*)]

(As amended Pub. L. 102-571, title I, § 107(13), Oct. 29, 1992, 106 Stat. 4499.)